REACH-IT Data Submission Manual

Part 4 - How to Pass Business Rule Verification ("Enforce Rules")

Document history

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1 How to use this manual

Chapters 2 and 3 give a short overview of the steps required to ensure that a dossier passes Business Rules for submissions under the REACH Regulation 1907/2006. This three page summary contains the basic information that you need to know. In the appendices you will find detailed information relevant to your specific situations.

2 Introduction

The aim of this document is to help ensure that companies can successfully submit a dossier under the REACH Regulation 1907/2006 through REACH-IT, and in particular to explain the initial checks that are made by REACH-IT to determine whether the dossier can be accepted for further processing.

Dossier types currently undergoing these checks and described in this manual include:

- Registrations
- Notifications for PPORD (Product and Process Orientated Research and Development) exemptions
- Inquiry dossiers

This document outlines how and why these checks are carried out. It also aims to give guidance on how to prepare the substance dataset and the dossier header in order to be able to successfully pass the business rule verification.

One substance, one registration: REACH operates on the principle of one substance, one registration. If you have more than one substance to register then you need to make a series of single registrations. If you have a number of substances with similar structure and/or properties a category approach can be used but it is still necessary to submit a separate registration dossier for each substance being registered. More information on categories is provided in Section D6 and D8.2.5 of the IUCLID 5 end user manual.

⚠ Note that ECHA will develop and apply new business rules when required. Please check the web page regularly for updates.

2.1 Business Rule Verification

2.1.1 What are business rules?

All dossiers submitted to ECHA undergo administrative checks, called “business rules”. The business rules are a set of pre-requisites that must be fulfilled before ECHA can establish that the dossier can be handled properly and that the required regulatory processes can be successfully carried out. The business rules are checked using the REACH-IT software, and exist for two reasons:

- Format: In order to be processed correctly, REACH-IT must establish whether the dossier in the correct IUCLID 5 format. For example, a PPORD notification must not be in the format of a registration dossier.
- Administrative: Before accepting a dossier for processing, ECHA must establish that it can be properly handled. This requires that certain administrative information has to be checked to ensure that it is consistent with the submission type. For example, if the dossier is an update following a regulatory request, but the reference number

provided for the previous submission is incorrect, it would be impossible to establish a link with the previous dossier. Under other circumstances, it might be unclear how the dossier should be invoiced.

A dossier can be accepted for processing by ECHA only if all of the relevant business rules are satisfied. After that, the submission can proceed to the next steps (e.g. technical completeness check (TCC) and invoicing). If the dossier submission fails at the business rule level, the dossier cannot be accepted for processing, and a new submission is required before any regulatory processes can be initiated.

2.1.2 Different types of business rules

The majority of business rules are checked automatically by REACH-IT. These are called 'Mandatory Business Rules'. However, once the Mandatory Business Rules have successfully passed, certain further Business Rules are carefully checked by ECHA staff. These are called 'Overrulable Business Rules'.

In case your dossier failed Mandatory Business Rules, you can see the results directly in your Submission Report. Overrulable Business Rule failures are sent to you by an official communication, available as a PDF in the 'Annotations' tab in your Submission Report.

For further details on how to access this information see Appendix 6.

2.1.3 Business rules versus TCC

The business rules check includes format validation and more specifically, includes a technical validation of information that is required for processing. This process is not part of the Technical Completeness Check as described in the REACH regulation.

2.1.4 Where can I find further information on dossier submission?

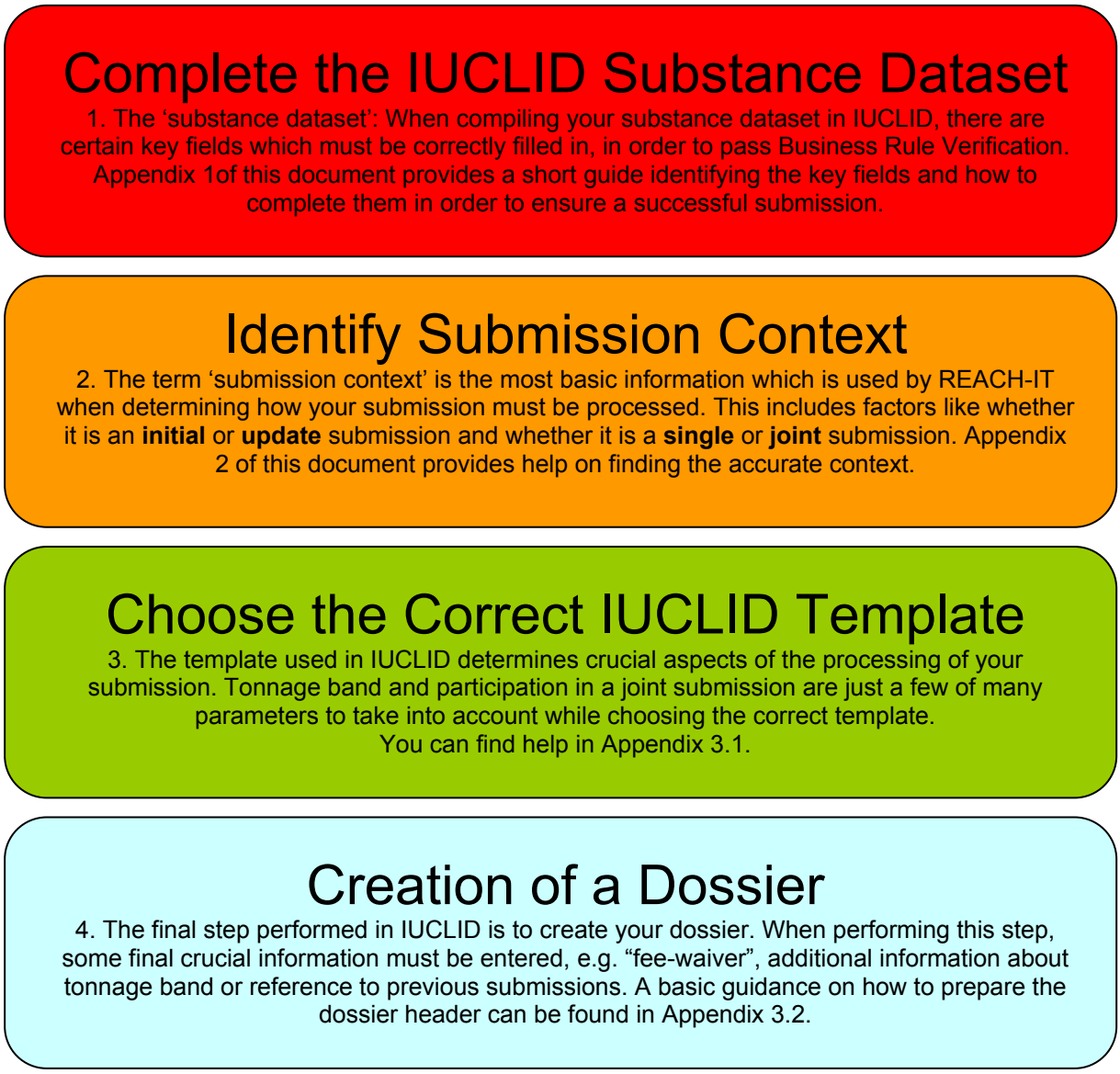
Further information on how to submit a notification or registration to ECHA is available on ECHA's website http://echa.europa.eu/reachit_en.asp. The information helps you to understand the topics covered and provides access to relevant documents, tools and web pages.

3 How to Pass Business Rules – IUCLID 5 preparations

This document is meant to be used as a "Business Rule Navigator", which will guide you through the basic steps of creating the substance dataset and the IUCLID dossier header. At the same time, it provides you with a basic understanding of Business Rule verification.

In essence there are four main steps to ensuring that a dossier can pass the business rule verification. These are outlined in Figure 1 below.

Figure 1: Four Steps of Passing Business Rule Verification


Complete the IUCLID Substance Dataset
1. The 'substance dataset': When compiling your substance dataset in IUCLID, there are certain key fields which must be correctly filled in, in order to pass Business Rule Verification. Appendix 1of this document provides a short guide identifying the key fields and how to complete them in order to ensure a successful submission.
Identify Submission Context
2. The term 'submission context' is the most basic information which is used by REACH-IT when determining how your submission must be processed. This includes factors like whether it is an initial or update submission and whether it is a single or joint submission. Appendix 2 of this document provides help on finding the accurate context.
Choose the Correct IUCLID Template
3. The template used in IUCLID determines crucial aspects of the processing of your submission. Tonnage band and participation in a joint submission are just a few of many parameters to take into account while choosing the correct template.
You can find help in Appendix 3.1.
Creation of a Dossier
4. The final step performed in IUCLID is to create your dossier. When performing this step, some final crucial information must be entered, e.g. "fee-waiver", additional information about tonnage band or reference to previous submissions. A basic guidance on how to prepare the dossier header can be found in Appendix 3.2.

For general guidance on dossier creation, refer to the IUCLID 5 User manual, section C.6 "Creating a dossier" and section D.8.2 "Creating dossiers".

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Appendix 1 Complete the IUCLID Substance Dataset

The substance dataset contains a number of data fields which are crucial. Regardless of the type of submission, the information for these fields needs to be present.

In addition, given parts of the IUCLID file only have to be populated in specific cases. Below you can find the general information and guidance for the most crucial sections in IUCLID to be filled out for a successful business rule validation.

Appendix 1.1 Legal Entity in REACH-IT and in IUCLID Dossier

In the process of creating a dataset, creating a dossier and submitting it, there are three instances where the legal entity needs to be indicated. To avoid any ambiguity, you have to ensure that all these legal entities are the same.

- Section 1.1: The substance dataset is linked to a specific IUCLID legal entity. This must be the same as the REACH-IT legal entity from which the dossier will be submitted.
- Dossier Creation: When creating the dossier you must ensure that you have selected the IUCLID legal entity which corresponds with the submitting legal entity in REACH-IT.
- REACH-IT: The account you use will determine the legal entity that ECHA will consider as associated with all the regulatory processes and/or communications concerning the submitted dossier.

If the three above mentioned legal entities are not the same, the submission will be rejected.

Appendix 1.2 Section 1.1 – Identification

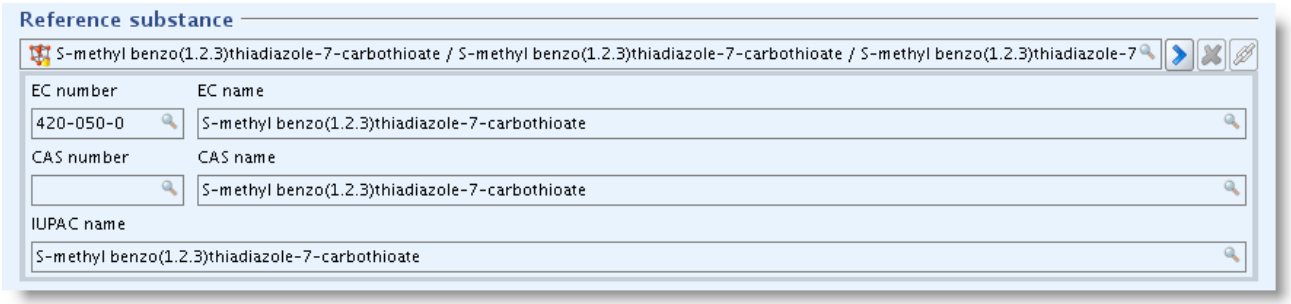
Section 1.1 in IUCLID is used for basic identification of both the substance and the submitting company.

If a Third party representative is included in the dossier, the company in question has to be already registered in REACH-IT as a “Third Party Representative”.

The Reference Substance has to be identified with at least one of the following identifiers:

- EC Number
- CAS Number
- IUPAC Name

Figure 2: Example for identifying the reference substance



Absence of the EC Number assigned to the substance will lead to Business Rules failures in the following cases:

- **The submission is an update**
- **The submission contains a valid Inquiry number in Section 1.3 (the EC number given in the inquiry result has to be in line with the one used in Section 1.1)**

The following information has to be taken into account, when choosing the correct "Role in the supply chain":

- If "Manufacturer" is selected, a production site in section 3.3 "Sites" must be provided.
- The role "Downstream user" cannot be selected if the submission only covers intermediates.
- If "Downstream user" is selected, "Substance in article" must be ticked in section 3.4 "Form in the supply chain".
- The role "Only representative" cannot be selected together with "Manufacturer" or "Importer".

Appendix 1.2.1 Downloading the EC number from REACH-IT

In case you were unable to provide an EC number in your initial submission, REACH-IT will have automatically assigned one. **This number must be used** in any subsequent updates. This automatically created EC Inventory entry can be downloaded in i5z IUCLID file format from REACH-IT.

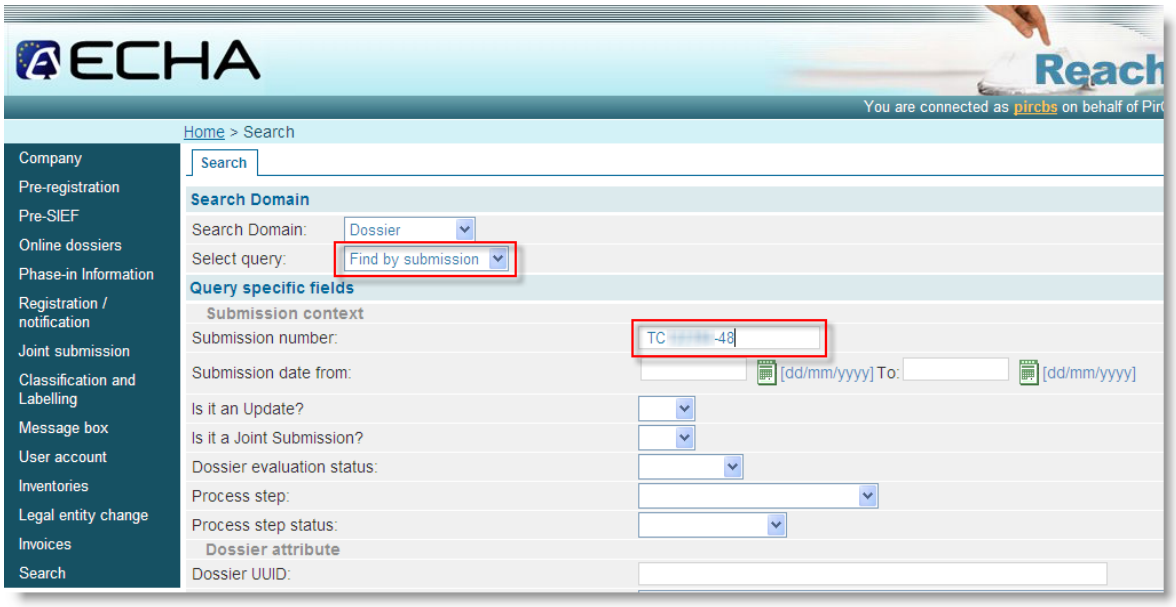
To download the EC number, please follow the steps below:

1. Log-in to REACH-IT and click on "Search" for "Dossier".

Figure 3: REACH-IT Home Screen

2. From the query list select “Find by submission” and enter the submission number of the dossier you wish to update into the appropriate field.

Figure 4: Searching for Dossier in REACH-IT



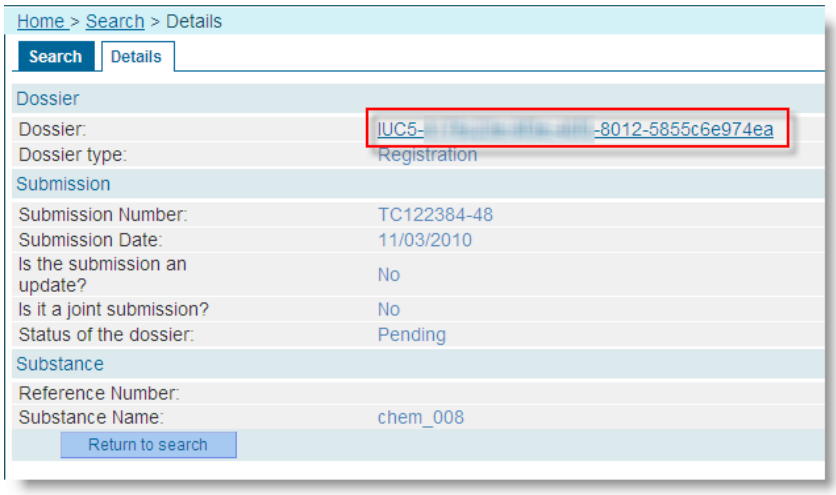
3. In the results field click on the UUID of the dossier.

Figure 5: Search Results in REACH-IT

Submission number	Submission date	Submission update	Status	Process step	Process step status	Dossier UUID	Dossier type	R
TC -48	11/03/2010	No	Pending	Pay Submission Fee	Started	IUC5- 8012-5855c6e974ea	Registration	

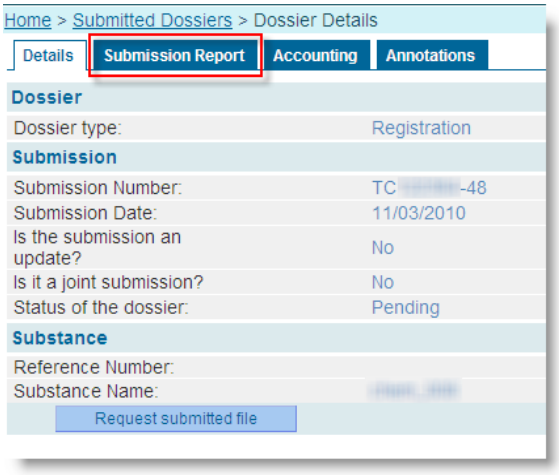
4. Click again on the Dossier’s UUID in the new page.

Figure 6: Dossier Details



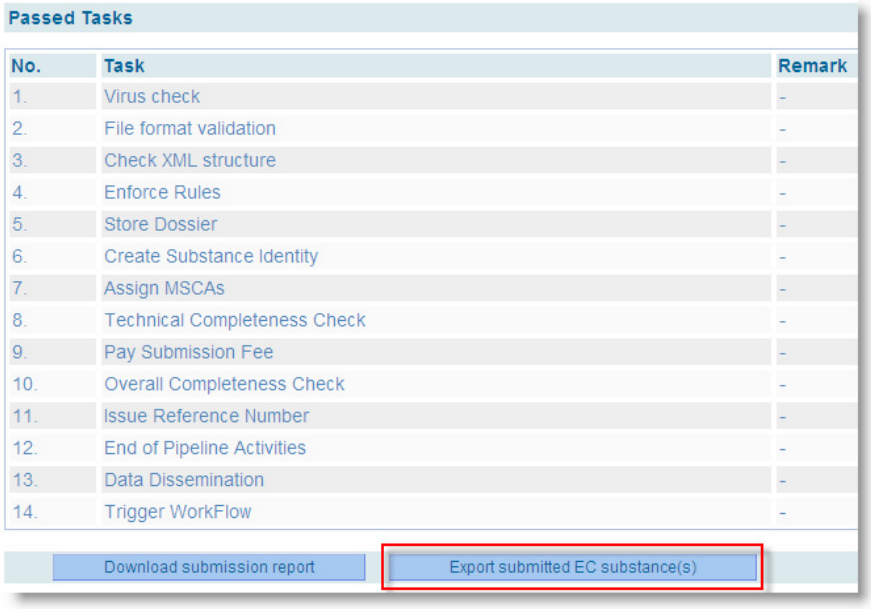
5. Choose the “Submission Report” tab.

Figure 7: Dossier Further Details



6. In the bottom of the Submission report you will find a button to export the EC Inventory Entry in IUCLID format.

Figure 8: Exporting EC number from REACH-IT


Passed Tasks
No. Task Remark
1. Virus check -
2. File format validation -
3. Check XML structure -
4. Enforce Rules -
5. Store Dossier -
6. Create Substance Identity -
7. Assign MSCAs -
8. Technical Completeness Check -
9. Pay Submission Fee -
10. Overall Completeness Check -
11. Issue Reference Number -
12. End of Pipeline Activities -
13. Data Dissemination -
14. Trigger WorkFlow -
Download submission report
Export submitted EC substance(s)

7. Import the downloaded i5z file into your IUCLID installation and use it in your update dossiers.

Appendix 1.3 Section 1.2 – Composition

A Substance is defined by its composition. The composition of a Substance can consist of constituents, impurities and additives. This section is a repeatable block section.

The following information has to be included in this section:

- In Section 1.2 in all cases:
    a. There must be at least one composition with at least one constituent

- Each constituent must have at least one identifier (EC number or CAS number or IUPAC name)

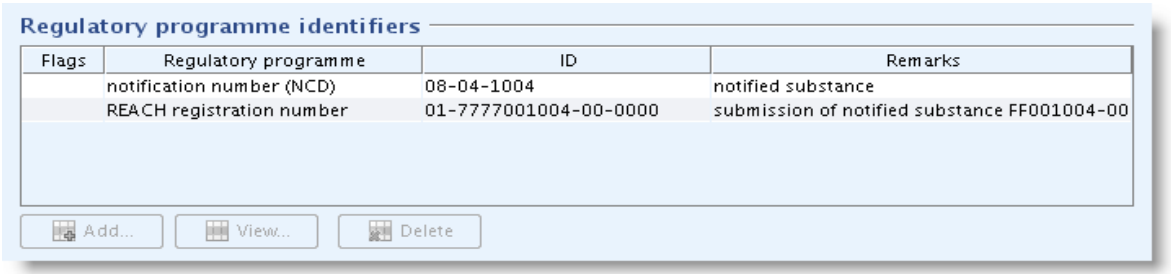
- Further requirements for Constituents:
  - For “mono constituent substance” there can only be one constituent included in Section 1.2 which has the same identity as given in Section 1.1
  - For “multi constituent substance” at least two constituents must be present. None of these constituents can be the same as the one used in Section 1.1. In exceptional cases, there can also be only one constituent present, but under these circumstances this constituent has to be the same as in Section 1.1.

Appendix 1.4 Section 1.3 – Identifiers

Certain regulatory identifiers must be included in Section 1.3.

- REACH Registration Number: Registration numbers are obtained by successfully registering a substance or by claiming a notified substance. The provided number has to belong to the submitting company, and has to point to the reference substance used in Section 1.1 of the dossier.
- Notification Number (NCD): If your registration number was granted by ECHA for a substance previously notified under Directive 67/548/EEC you must in provide the Notification (NCD) Number in addition to the registration number. The dossier’s submitting company has to match with the company who claimed the notification in REACH-IT. Also, the substance must be the same in the dossier and in the notification.
- REACH Pre-registration number: When provided the indicated pre-registration number has to belong to the submitting company.
- REACH PPORD Notification Number: The provided number has to belong to the submitting company, and has to point to the reference substance used in Section 1.1 of the dossier.
- REACH Inquiry Number: When provided the number has to belong to the submitting company and the EC number which was provided by ECHA after this inquiry must match the one used in Section 1.1.

Figure 9: Regulatory programme identifiers in Section 1.3



Appendix 1.5 Section 1.5 – Joint submission

The information of the Joint Submission is completely derived from REACH-IT and any information in Section 1.5 is not taken into account. Section 1.5 can be used for your own administrative purposes, but it is important to note that the consistency of any information in this section of IUCLID will not be verified against the information derived from REACH-IT.

Appendix 1.6 Section 2.1 – GHS and Section 2.2 – DSD – DPD

In a registration dossier the classification and labelling information must be provided in Section 2. In case of a Joint Submission this information will be provided by the lead and is not expected to be in the member dossier, unless in the case Section 2 is part of the information for which an opt-out applies.

The format of the classification depends on the date of submission as follows:

- Submission before 01/12/2010: the dossier must contain either only the DSD (Section 2.2) or both GHS (Section 2.1) and DSD (Section 2.2). It is strongly recommended that you include both sections to prevent updating the dossier to include the CLP information.
- Submission after 01/12/2010: The dossier must contain GHS (Section 2.1) classification.

For more information on Classification and Labelling, please see Data Submission Manual 5 (available at http://echa.europa.eu/doc/reachit/compl_tech_dossier_manual.pdf)

Appendix 1.7 Section 3.3 – Sites

This section is a repeatable block section, which offers the possibility to list all sites where the Substance is produced and/or used. This is done by creating for each site a link with the relevant information stored in the Legal entity site inventory. The minimum data required is the country, where the site is located. Please note that in the case of an importer no information is required in this section, however, if a site is provided, the same requirement applies.

Appendix 1.8 Section 3.4 – Form in the supply chain

If “Downstream user” is selected in Section 1.1 “Role in the supply chain”, then the “Substance in article” box must be marked.

Appendix 2 Identify Submission Context

The submission context is the regulatory context in which you make the submission. An example could be the “initial submission of a 1-10 tpa dossier as a member of a Joint Submission”. This context defines which information must be available in the dossier to enable it to be processed.

The main factors in identifying the submission context is if the submission is a “Single Submission” or “Joint Submission”, or initial or update. In case of a joint submission, there are further options, as the dossier can be a “Lead” or a “Member”. A submission can be:

- Initial: no Registration number has been assigned to the submitting company for this substance.
- Spontaneous Update: the substance has already been successfully registered, but an update is needed. Possible reasons for the update can be found in section Appendix 5.3.3.2.

- Requested Update: a submission has failed Technical Completeness Check, or after successful registration further information was requested (e.g. compliance check).

After identifying your submission, you can follow the links to the specific annexes, where you'll find examples of how your dossier header should look like, together with a checklist of special issues you have to take care of.

	Single Submission	Joint Submission Lead	Joint Submission Member
Initial	Appendix 4.1	Appendix 4.4	Appendix 4.7
Spontaneous Update	Appendix 4.2	Appendix 4.5	Appendix 4.8
Requested Update	Appendix 4.3	Appendix 4.6	Appendix 4.9

Appendix 3 Creating the dossier

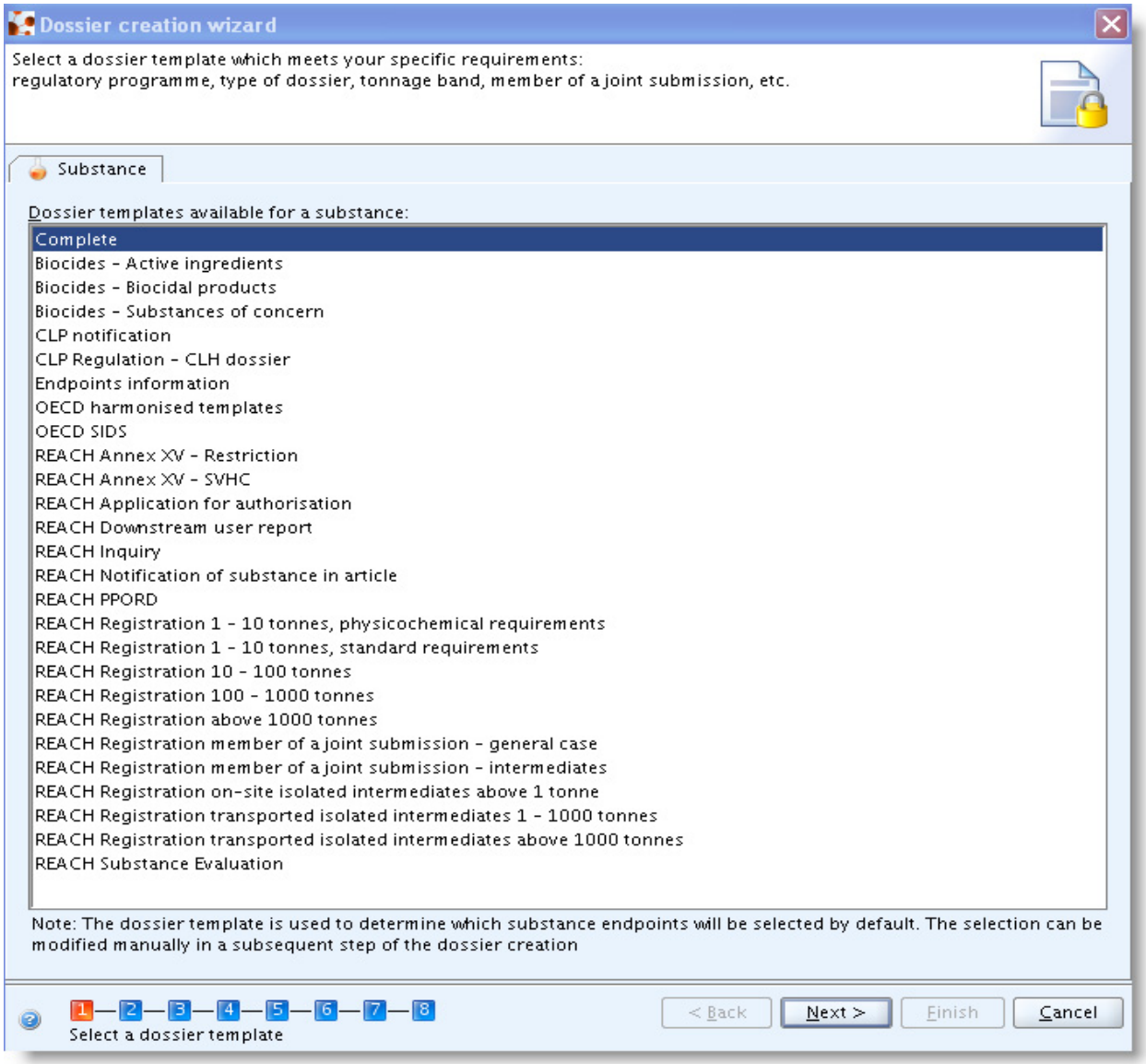
Appendix 3.1 Choosing the correct IUCLID 5 template

Choosing the correct dossier template is an important step in a successful submission, as the template indicates the tonnage band of the submission and determines amongst many other things which substance endpoints will be selected by default to export into your dossier.

Before exporting the data you have to make sure that the template selected corresponds with the intended submission (e.g. correct dossier type (Inquiry, PPORD, Registration, etc.) correct tonnage band). Note that in the case of a lead dossier in a Joint Submission, additional information about tonnage band has to be provided, more information about that can be found in Appendix 5.2.

Please note there is no specific template available for "lead" of Joint Submission, as for those cases the generic registration (both general and intermediate) and classification & labelling templates should be used. The information about the joint submission has to be indicated in those cases in the dossier header (Appendix 5.2).

Figure 10: Dossier Template Selection in IUCLID


Dossier creation wizard
Select a dossier template which meets your specific requirements:
regulatory programme, type of dossier, tonnage band, member of a joint submission, etc.
Substance
Dossier templates available for a substance:
Complete
Biocides - Active ingredients
Biocides - Biocidal products
Biocides - Substances of concern
CLP notification
CLP Regulation - CLH dossier
Endpoints information
OECD harmonised templates
OECD SIDS
REACH Annex XV - Restriction
REACH Annex XV - SVHC
REACH Application for authorisation
REACH Downstream user report
REACH Inquiry
REACH Notification of substance in article
REACH PPORD
REACH Registration 1 - 10 tonnes, physicochemical requirements
REACH Registration 1 - 10 tonnes, standard requirements
REACH Registration 10 - 100 tonnes
REACH Registration 100 - 1000 tonnes
REACH Registration above 1000 tonnes
REACH Registration member of a joint submission - general case
REACH Registration member of a joint submission - intermediates
REACH Registration on-site isolated intermediates above 1 tonne
REACH Registration transported isolated intermediates 1 - 1000 tonnes
REACH Registration transported isolated intermediates above 1000 tonnes
REACH Substance Evaluation
Note: The dossier template is used to determine which substance endpoints will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation
1 — 2 — 3 — 4 — 5 — 6 — 7 — 8
Select a dossier template
< Back
Next >
Finish
Cancel

Context	IUCLID 5 Template	Dossier type in REACH-IT
Individual submission dossier or Lead dossier		
Standard Registration	Registration template with the corresponding tonnage band (e.g. REACH Registration 10-100 tonnes)	Registration
Standard Registration + Intermediate(s)	Registration template with the corresponding tonnage band (e.g. REACH Registration 10-100 tonnes)	Registration
Registration of one type of intermediate (i.e. On-Site OR Transported)	Intermediate template with the corresponding type and tonnage band (e.g. REACH Registration On-Site Isolated Intermediates above 1 tonne)	Registration of transported isolated intermediate or Registration of on-site isolated intermediate
Combination of Intermediates	Transported Isolated Intermediate template with the corresponding tonnage band (e.g. REACH Registration transported isolated intermediates 1-1000 tonnes)	Registration of transported isolated intermediate
Member dossier		
Standard Registration	REACH Registration member of a joint submission – general case	Registration
Standard Registration + Intermediate(s)	REACH Registration member of a joint submission – general case	Registration
Registration of one type of intermediate (i.e. On-Site OR Transported)	REACH Registration member of a joint submission – intermediates	Registration of transported isolated intermediate or Registration of on-site isolated intermediate
Combination of Intermediates	REACH Registration member of a joint submission – Intermediates	Registration of transported isolated intermediate

Appendix 3.2 Creation of a Dossier from a substance dataset

- Dossier header: The dossier header is derived from information entered when creating the dossier. It consists of information used for administrative purposes and is completed by the applicant when preparing his dossier from the substance data set.

This chapter explains how to complete the IUCLID 5 dossier header information.

The information contained in the dossier header is crucial for Business Rules checking when you submit your dossier. Missing or incorrect information can result in the dossier not being accepted for further processing. For example, it might be unclear whether the dossier is intended as an update of a previous registration due to a tonnage band increase, or an update due to a request for further information after a first completeness check under Article 20 of REACH.

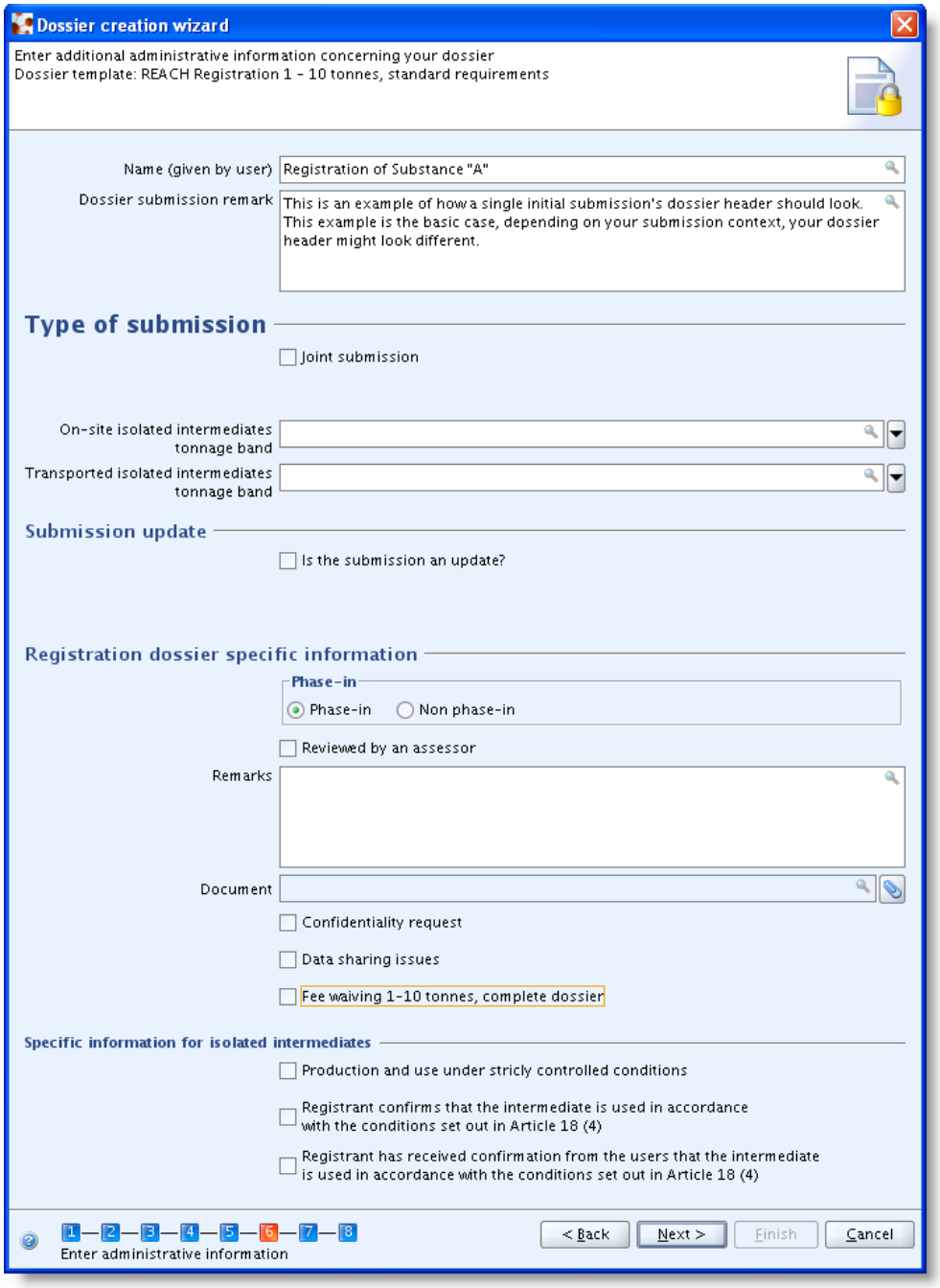
Because it is critical that ECHA clearly understands both the type of dossier and the specific circumstances behind the submission, REACH-IT will not process the dossier if this information is unclear and/or incorrect. Depending on the submission context

Appendix 4 Completing the dossier header

Having identified your submission context according to Appendix 2, the following subchapters explain how to take the final step during dossier creation for each submission context. In case further information is needed, go to Appendix 5.

Appendix 4.1 Single, Initial Submission

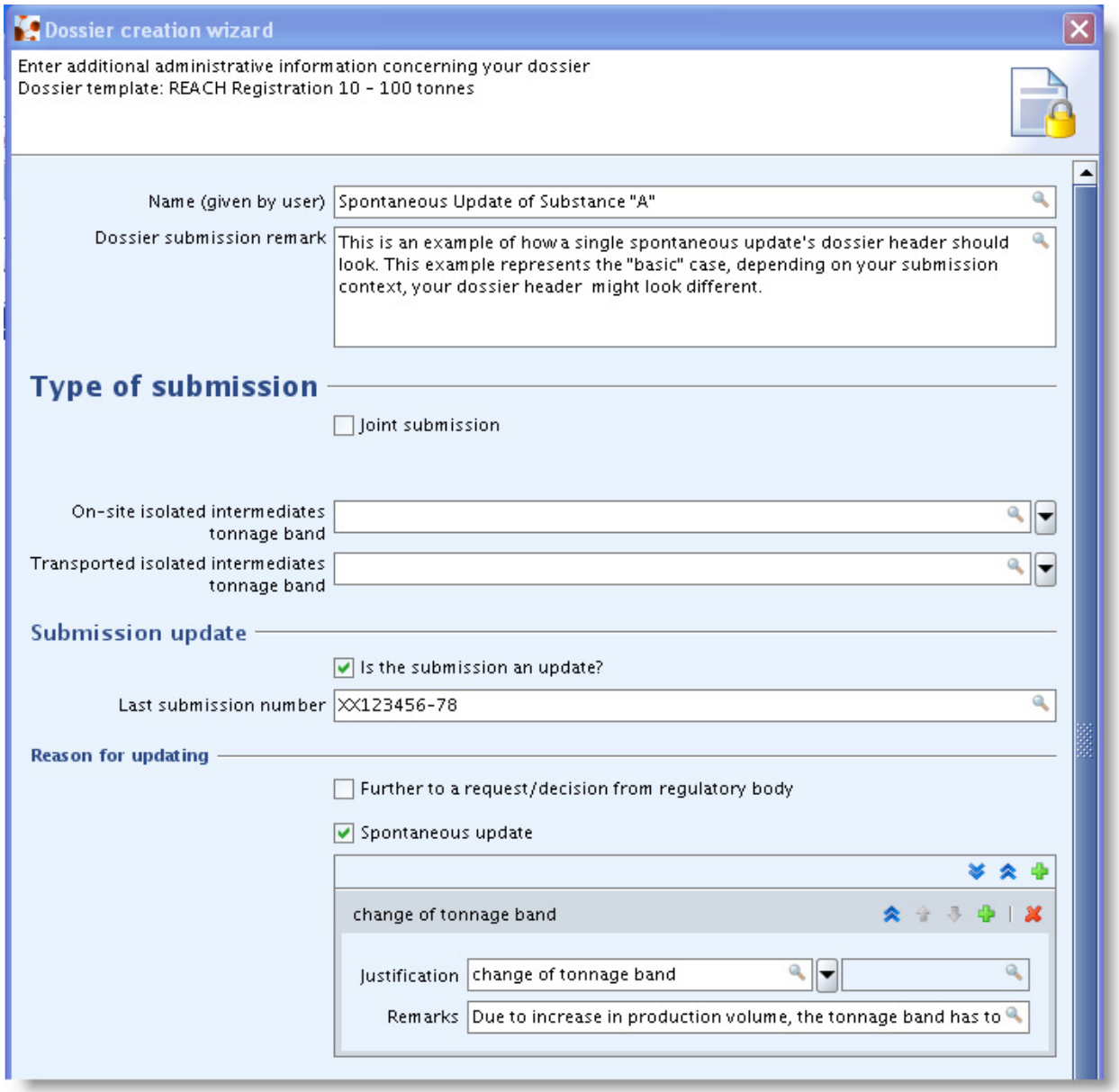
Figure 11: Single, Initial Submission


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a single initial submission's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Submission update
Is the submission an update?
Registration dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality request
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Specific information for isolated intermediates
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔
1, On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		4, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
2, Was the submission reviewed by an assessor? This information is not compulsory.		5, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
3, Do you want to claim confidentiality for the Tonnage Band of the submission? Appendix 5.4.1			

Appendix 4.2 Single Submission, Spontaneous Update

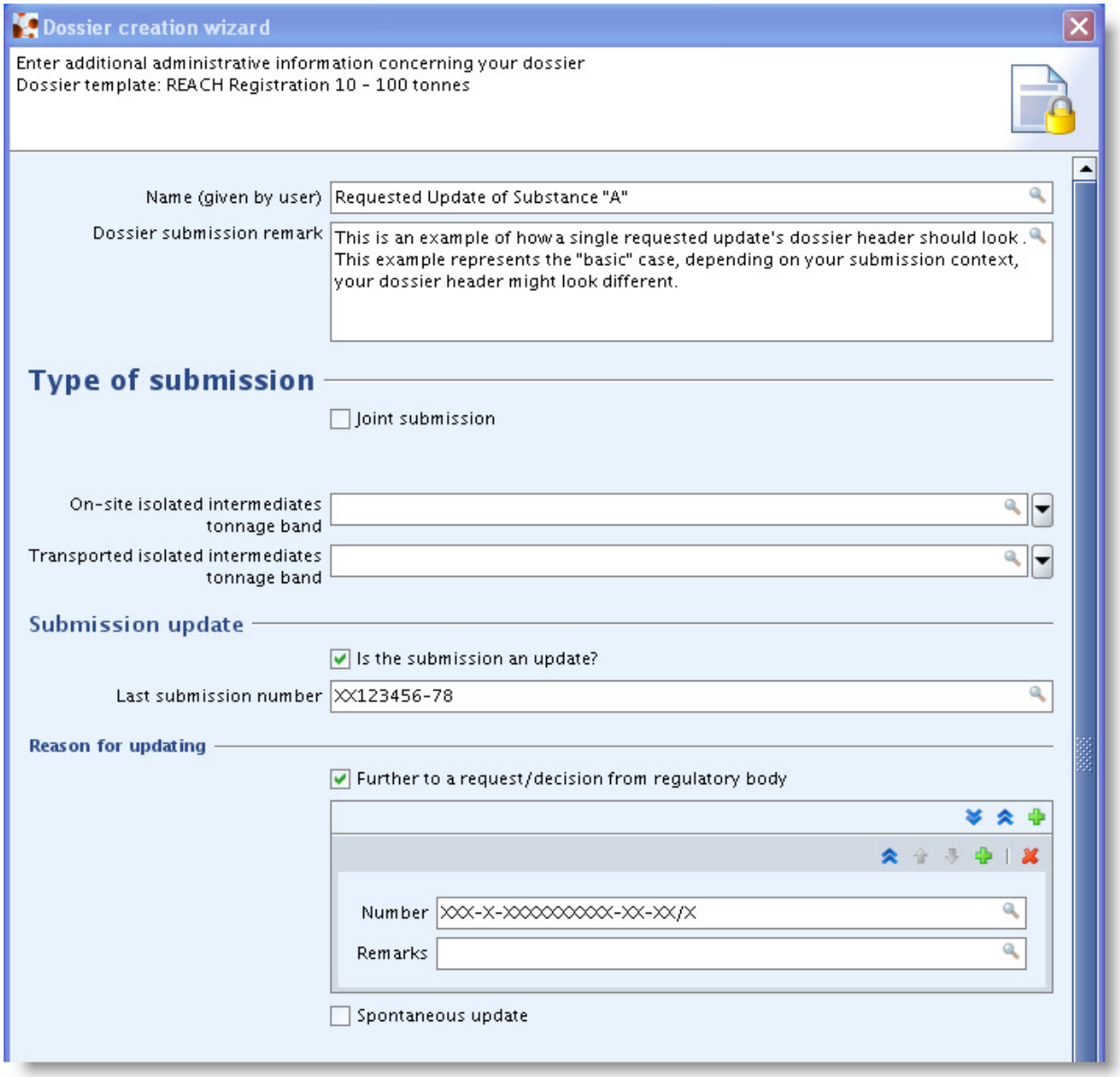
Figure 12: Single Submission, Spontaneous Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 10 - 100 tonnes
Name (given by user)
Spontaneous Update of Substance "A"
Dossier submission remark
This is an example of how a single spontaneous update's dossier header should look. This example represents the "basic" case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Submission update
Is the submission an update?
Last submission number
XX123456-78
Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Due to increase in production volume, the tonnage band has to

Checklist	✔	Checklist	✔
1, On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		5, Do you want to claim confidentiality for the Tonnage Band of the submission? Appendix 5.4.1	
2, Last submission number must be indicated. For a spontaneous update, this will be the submission number associated with the most recent registration for that substance. (For registrations derived from a NONS claim and other special cases, see Appendix 5.3)		6, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
3, Justification for the spontaneous update must be provided. Chapter Appendix 5.3.3.2		7, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
4, Was the submission reviewed by an assessor? This information is not compulsory.		8, Make sure that you are using the assigned EC number. Appendix 1.2.1	

Appendix 4.3 Single Submission, Requested Update

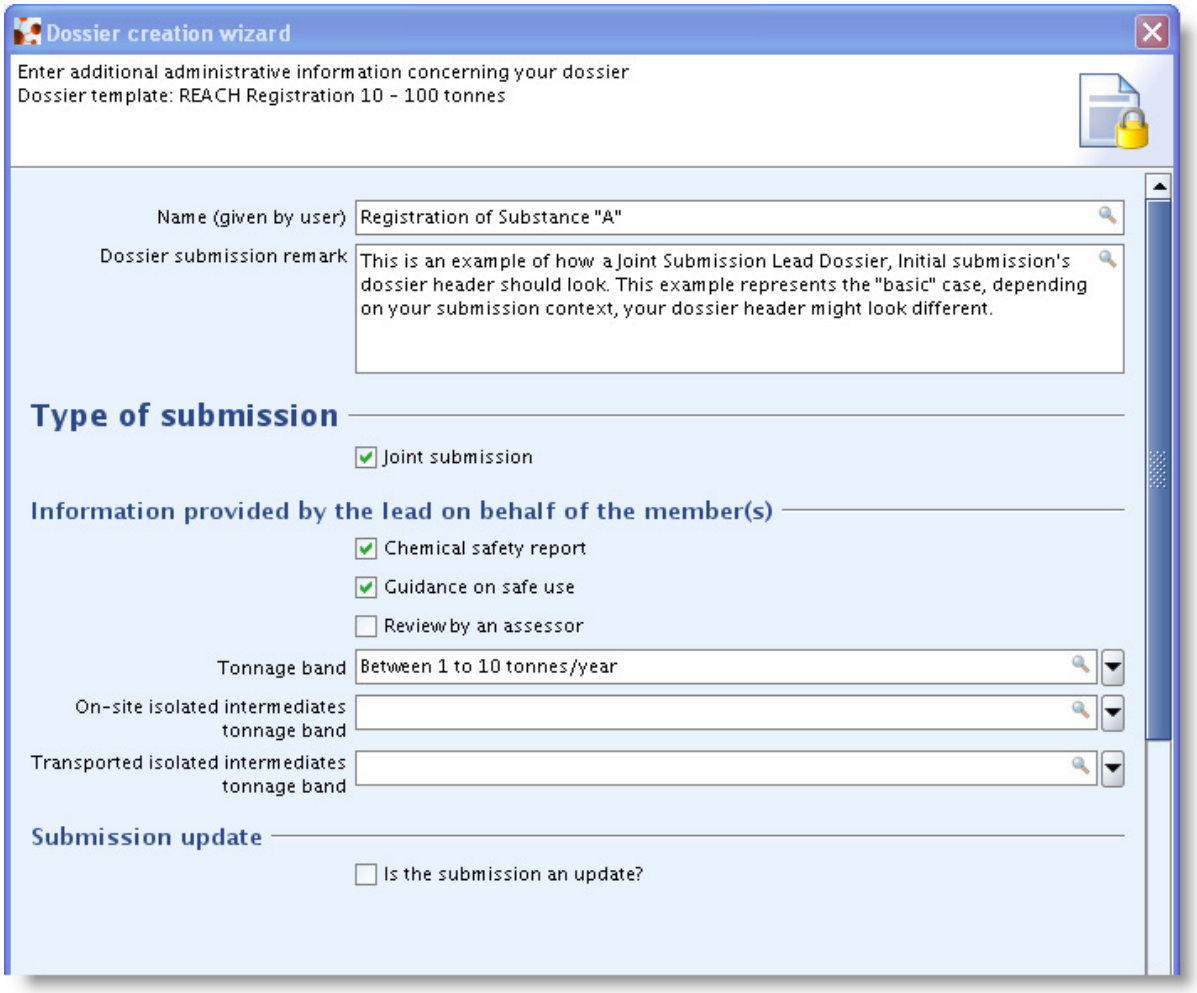
Figure 13: Single Submission, Requested Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 10 - 100 tonnes
Name (given by user)
Requested Update of Substance "A"
Dossier submission remark
This is an example of how a single requested update's dossier header should look. This example represents the "basic" case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Submission update
Is the submission an update?
Last submission number
XX123456-78
Reason for updating
Further to a request/decision from regulatory body
Number
XXX-X-XXXXXXXXX-XX-XX/X
Remarks
Spontaneous update

Checklist	✔	Checklist	✔
1, On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		6, If the Requested Update is for a previously registered substance, make sure that the required regulatory identifiers were included in Section 1.3 of your substance dataset. Appendix 1.4	
2, Transported Isolated Intermediate Tonnage Band		7, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
3, Last submission number must be indicated. For a Technical Completeness Check (TCC) update (i.e. further information being submitted following a TCC failure), this will be the submission number associated with the dossier that failed TCC. (For other types of regulatory update see Appendix 5.3)		8, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
4, The Communication Number must be indicated. In the case of a TCC failure this will be the communication number provided in the letter which requested further information. For further information, please see Appendix 5.3.1 or Appendix 5.3.3.1.		9, Make sure that you are using the assigned EC number. Appendix 1.2.1	
5, Was the submission reviewed by an assessor This information is not compulsory.		10, Do you want to claim confidentiality for the Tonnage Band of the submission? Appendix 5.4.1	

Appendix 4.4 Joint Submission Lead, Initial Submission

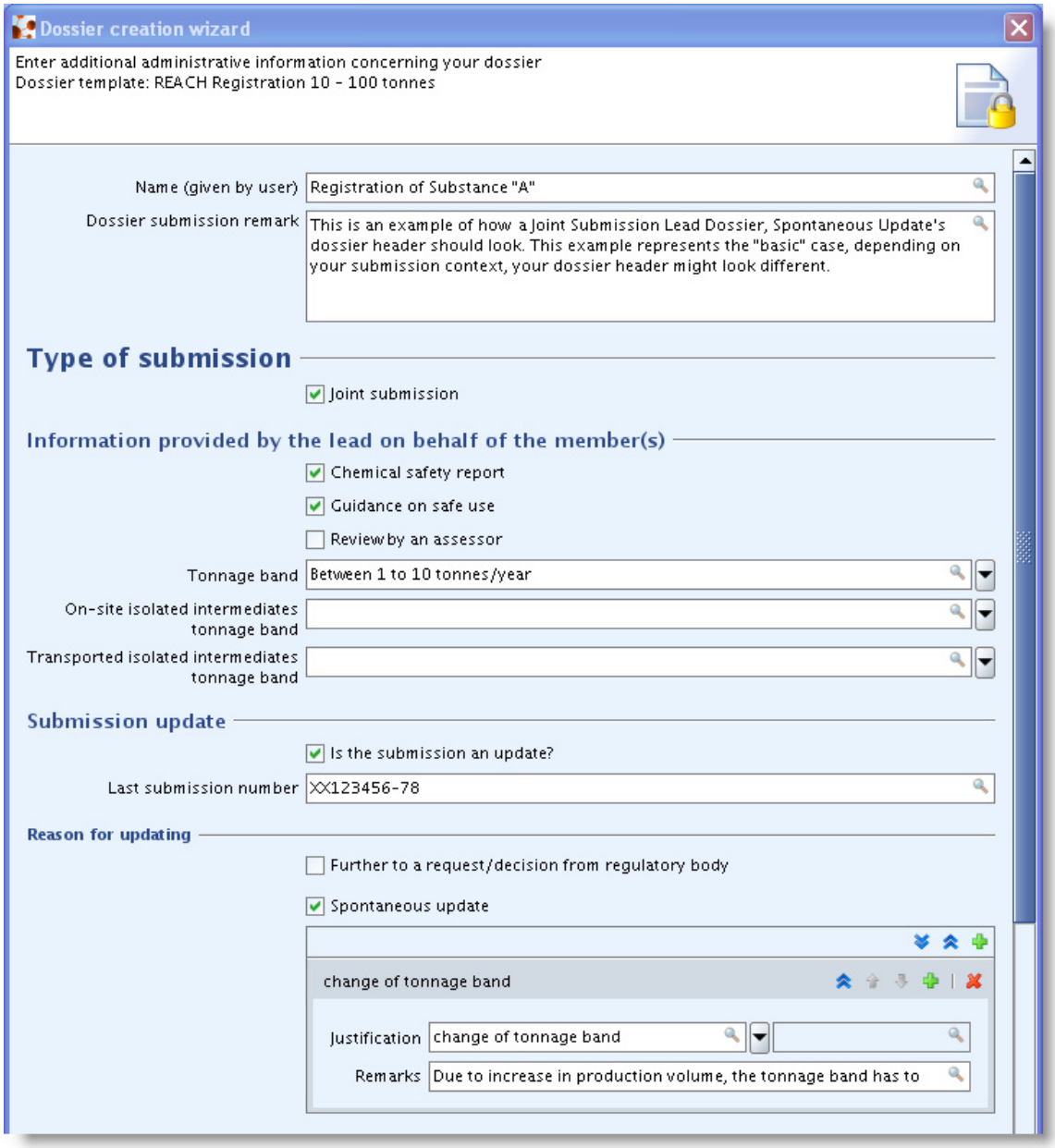
Figure 14: Joint Submission Lead, Initial Submission


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 10 - 100 tonnes
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a Joint Submission Lead Dossier, Initial submission's dossier header should look. This example represents the "basic" case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band
Between 1 to 10 tonnes/year
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Submission update
Is the submission an update?

Checklist	✔	Checklist	✔
1, Joint submission checkbox must be ticked Appendix 5.2		6, Do you want to claim confidentiality for the Tonnage Band of the submission? Appendix 5.4.1	
2, “Chemical Safety Report”: tick this box if you are supplying the CSR on behalf of members.		7, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
3, “Guidance on Safe Use”: tick this box if you are supplying the Guidance on Safe Use on behalf of members.		8, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
4, “Review by Assessor”: this information is not part of the Business Rule check.		9, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
5, Information on tonnage band: When acting as the lead in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists. Note: The overall tonnage band of the Joint Submission is determined by the IUCLID 5 template that was used			

Appendix 4.5 Joint Submission Lead, Spontaneous Update

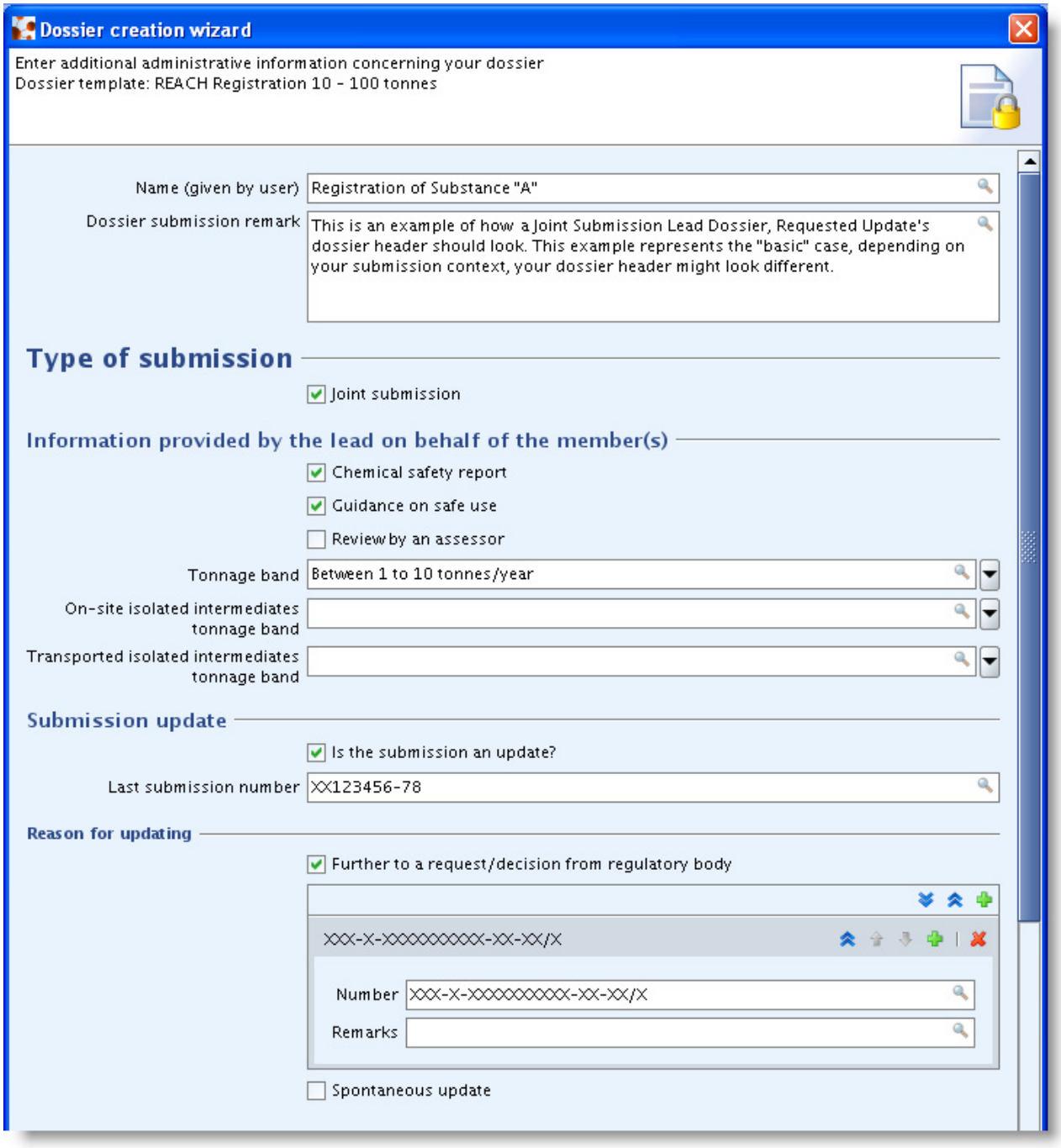
Figure 15: Joint Submission Lead, Spontaneous Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 10 - 100 tonnes
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a Joint Submission Lead Dossier, Spontaneous Update's dossier header should look. This example represents the "basic" case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band
Between 1 to 10 tonnes/year
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Submission update
Is the submission an update?
Last submission number
XX123456-78
Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Due to increase in production volume, the tonnage band has to

Checklist	✔	Checklist	✔
1, Joint Submission checkbox must be ticked. Appendix 5.2		7, Last submission number must be indicated. For a spontaneous update, this will be the submission number associated with the most recent registration for that substance. (For registrations derived from a NONS claim and other special cases, see Appendix 5.3)	
2, “Chemical Safety Report”: tick this box if you are supplying the CSR on behalf of members.		8, Justification for Spontaneous Update must be provided. Chapter Appendix 5.3.3.2	
3, “Guidance on Safe Use”: tick this box if you are supplying the Guidance on Safe Use on behalf of members.		9, Do you want to claim confidentiality for the Tonnage Band of the submission? Appendix 5.4.1	
4, “Review by Assessor”: this information is not part of the Business Rule check.		10, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
5, Information on tonnage band: When acting as the lead in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists. Note: The overall tonnage band of the Joint Submission is determined by the IUCLID 5 template that was used		11, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
6, Make sure that you are using the assigned EC number. Appendix 1.2.1		12, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	

Appendix 4.6 Joint Submission Lead, Requested Update

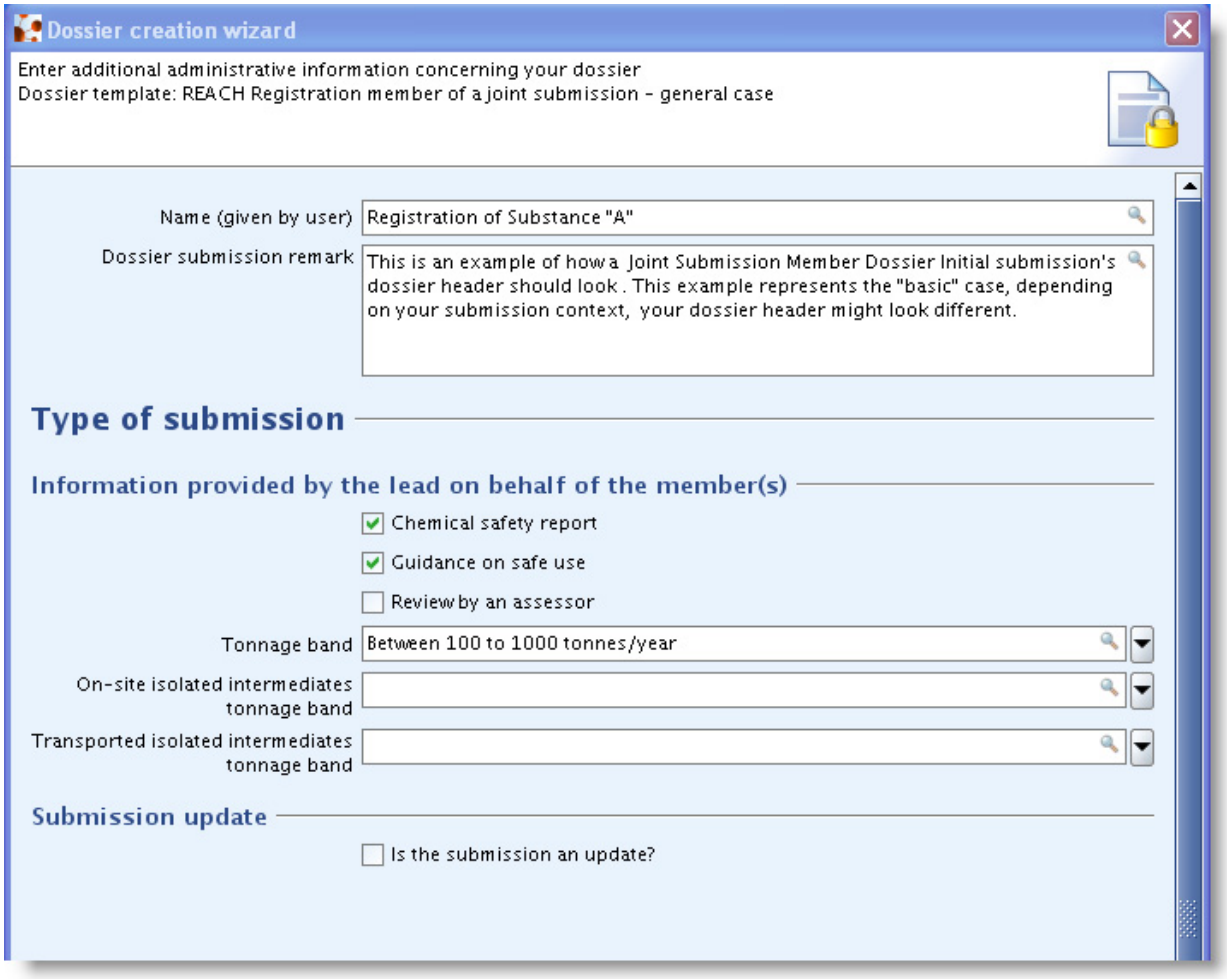
Figure 16: Joint Submission Lead, Requested Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 10 - 100 tonnes
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a Joint Submission Lead Dossier, Requested Update's dossier header should look. This example represents the "basic" case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band
Between 1 to 10 tonnes/year
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Submission update
Is the submission an update?
Last submission number
XX123456-78
Reason for updating
Further to a request/decision from regulatory body
XXX-X-XXXXXXXXX-XX-XX/X
Number
XXX-X-XXXXXXXXX-XX-XX/X
Remarks
Spontaneous update

Checklist	✔	Checklist	✔
Joint Submission checkbox must be ticked. Appendix 5.2		8, The Communication Number must be indicated. In the case of a TCC failure this will be the communication number provided in the letter which requested further information. For further information, please see Appendix 5.3.1 or Appendix 5.3.3.1.	
2, “Chemical Safety Report”: tick this box if you are supplying the CSR on behalf of members.		9, Do you want to claim confidentiality for the Tonnage Band of the submission? Appendix 5.4.1	
3, “Guidance on Safe Use”: tick this box if you are supplying the Guidance on Safe Use on behalf of members.		10, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
4, “Review by Assessor”: this information is not part of the Business Rule check.		11, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
5, Information on tonnage band: When acting as the lead in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists. Note: The overall tonnage band of the Joint Submission is determined by the IUCLID 5 template that was used		12, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
6, Make sure that you are using the assigned EC number. Appendix 1.2.1		13, If the Requested Update is for a previously registered substance, make sure that the required regulatory identifiers were included in Section 1.3 of your substance dataset. Appendix 1.4	
7, Last submission number must be indicated. For a Technical Completeness Check (TCC) update (i.e. further information being submitted following a TCC failure), this will be the submission number associated with the dossier that failed TCC. (For other types of regulatory update see Appendix 5.3)			

Appendix 4.7 Joint Submission Member, Initial Submission

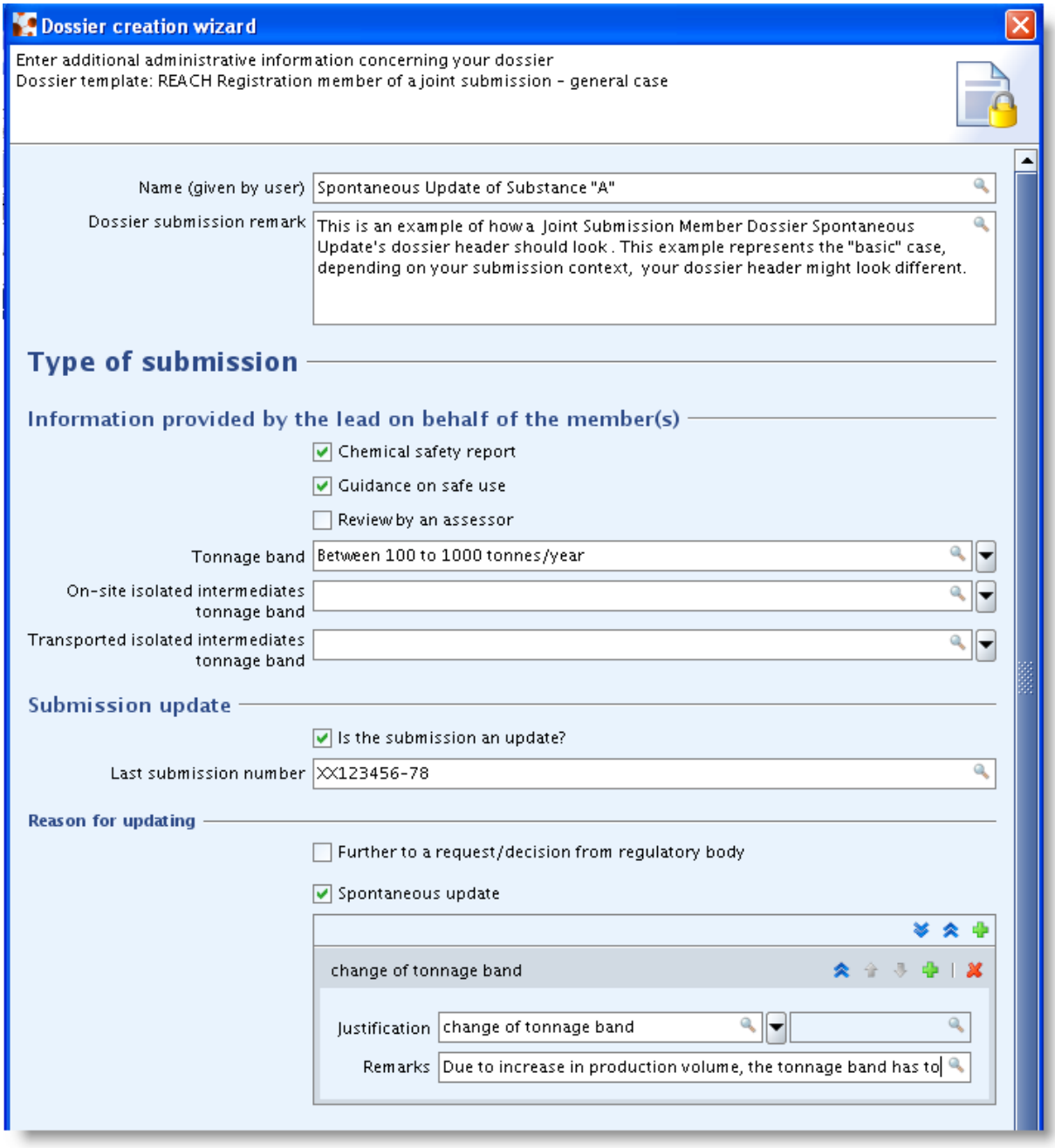
Figure 17: Joint Submission Member, Initial Submission


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration member of a joint submission - general case
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a Joint Submission Member Dossier Initial submission's dossier header should look. This example represents the "basic" case, depending on your submission context, your dossier header might look different.
Type of submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band
Between 100 to 1000 tonnes/year
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Submission update
Is the submission an update?

Checklist	✔	Checklist	✔
Joint Submission checkbox must be ticked. Appendix 5.2		6, Do you want to claim confidentiality for the Tonnage Band of the submission? Appendix 5.4.1	
2, “Chemical Safety Report”: tick this box if the CSR was supplied by the lead on your behalf.		7, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
3, “Guidance on Safe Use”: tick this box if the Guidance on Safe Use was supplied by the lead on your behalf.		8, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
4, “Review by Assessor”: this information is not part of the Business Rule check.		9, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
5, Information on tonnage band: When acting as a member in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.			

Appendix 4.8 Joint Submission Member, Spontaneous Update

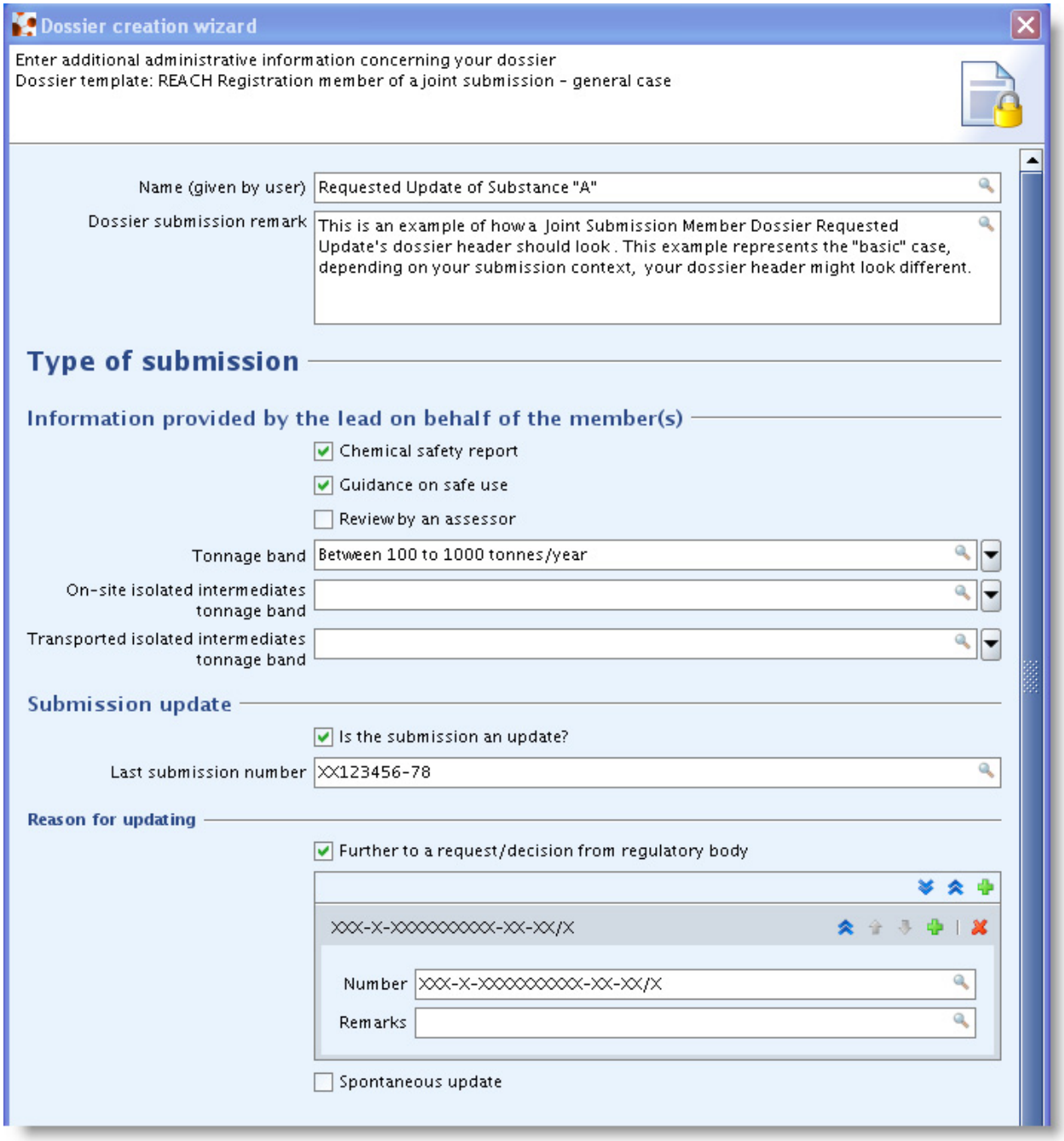
Figure 18: Joint Submission Member, Spontaneous Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration member of a joint submission - general case
Name (given by user)
Spontaneous Update of Substance "A"
Dossier submission remark
This is an example of how a Joint Submission Member Dossier Spontaneous Update's dossier header should look. This example represents the "basic" case, depending on your submission context, your dossier header might look different.
Type of submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band
Between 100 to 1000 tonnes/year
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Submission update
Is the submission an update?
Last submission number
XX123456-78
Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Due to increase in production volume, the tonnage band has to

Checklist	✔	Checklist	✔
1, Joint Submission checkbox must be ticked. Appendix 5.2		7, Justification for Spontaneous Update must be provided. Chapter Appendix 5.3.3.2	
2, “Chemical Safety Report”: tick this box if the CSR was supplied by the lead on your behalf.		8, Do you want to claim confidentiality for the Tonnage Band of the submission? Appendix 5.4.1	
3, “Guidance on Safe Use”: tick this box if the Guidance on Safe Use was supplied by the lead on your behalf.		9, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
4, “Review by Assessor”: this information is not part of the Business Rule check.		10, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
5, Information on tonnage band: When acting as a member in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		11, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
6, Last submission number must be indicated. For a spontaneous update, this will be the submission number associated with the most recent registration for that substance. (For registrations derived from a NONS claim and other special cases, see Appendix 5.3)		12, Make sure that you are using the assigned EC number. Appendix 1.2.1	

Appendix 4.9 Joint Submission Member, Requested Update

Figure 19: Joint Submission Member, Requested Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration member of a joint submission - general case
Name (given by user)
Requested Update of Substance "A"
Dossier submission remark
This is an example of how a Joint Submission Member Dossier Requested Update's dossier header should look. This example represents the "basic" case, depending on your submission context, your dossier header might look different.
Type of submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band
Between 100 to 1000 tonnes/year
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Submission update
Is the submission an update?
Last submission number
XX123456-78
Reason for updating
Further to a request/decision from regulatory body
XXX-X-XXXXXXXXXX-XX-XX/X
Number
XXX-X-XXXXXXXXXX-XX-XX/X
Remarks
Spontaneous update

Checklist	✔	Checklist	✔
1, The Joint Submission checkbox must be ticked. Appendix 5.2		8, Do you want to claim confidentiality for the Tonnage Band of the submission? Appendix 5.4.1	
2, “Chemical Safety Report”: tick this box if the CSR was supplied by the lead on your behalf.		9, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
3, “Guidance on Safe Use”: tick this box if the Guidance on Safe Use was supplied by the lead on your behalf.		10, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
4, “Review by Assessor”: this information is not part of the Business Rule check.		11, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
5, Information on tonnage band: When acting as a member in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		12, Make sure that you are using the assigned EC number. Appendix 1.2.1	
6, Last submission number must be indicated. For a Technical Completeness Check (TCC) update (i.e. further information being submitted following a TCC failure), this will be the submission number associated with the dossier that failed TCC. (For other types of regulatory update see Appendix 5.3)		13, If the Requested Update is for a previously registered substance, make sure that the required regulatory identifiers were included in Section 1.3 of your substance dataset. Appendix 1.4	
7, The Communication Number must be indicated. In the case of a TCC failure this will be the communication number provided in the letter which requested further information. For further information, please see Appendix 5.3.1 or Appendix 5.3.3.1.			

Appendix 5 Further information on the IUCLID 5 Dossier Header

The dossier header has a significant impact:

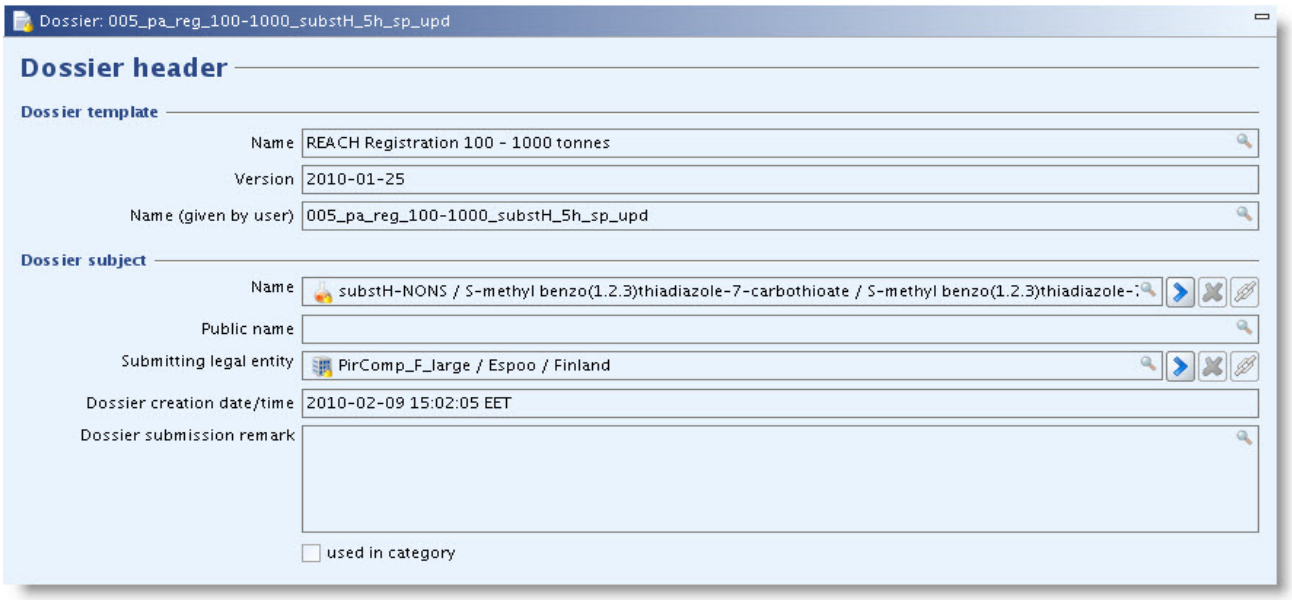
- On the processing of the dossier
- On the calculation of fees and preparation of the invoice.

During the IUCLID 5 dossier creation procedure, the dossier creation wizard requests the user to “Enter additional administrative information concerning your dossier” in the 6th step.

To create a dossier in IUCLID 5, you should start from the IUCLID 5 substance dataset, select the template corresponding to your submission (for e.g. REACH Registration 10 - 100 tonnes, REACH PPORD, …), follow the dossier creation wizard guide.

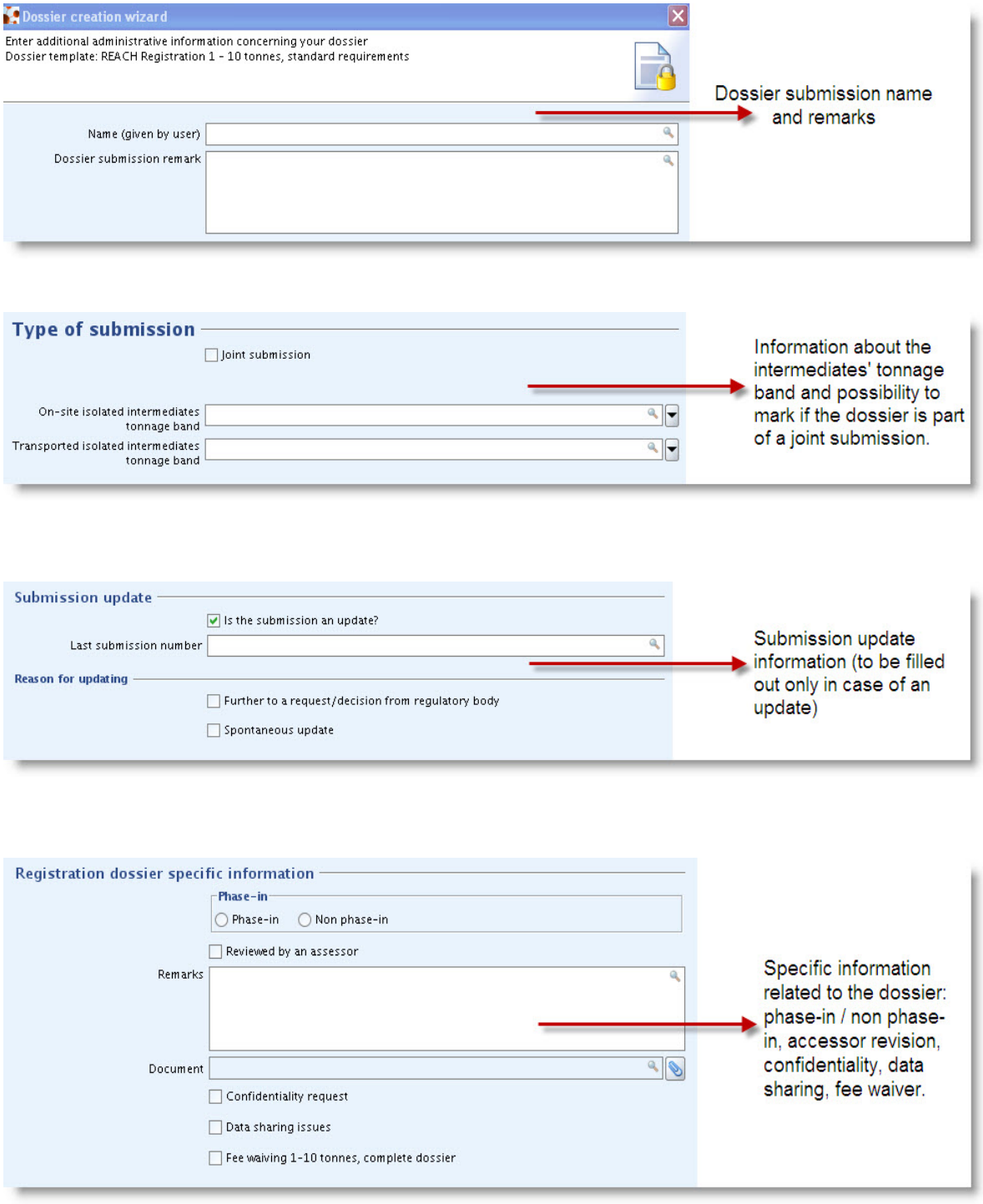
This information will then be embedded in the IUCLID 5 dossier header. Here below an example (Figure 20) of how a dossier header appears once the dossier is created.

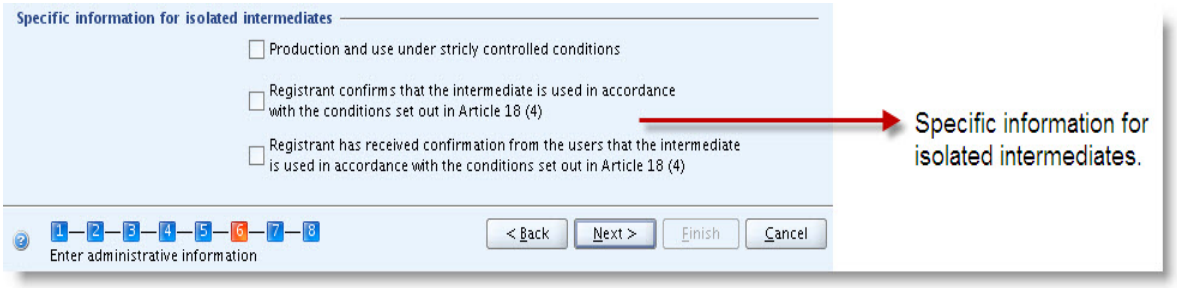
Figure 20: Dossier header in IUCLID 5



In the following pages, a detailed guide on how to fill in properly the information requested during the 6th step of the dossier creation wizard is given. The screen at this step is divided in five parts (Figure 21).

Figure 21: Step 6 of the Dossier Creation Wizard

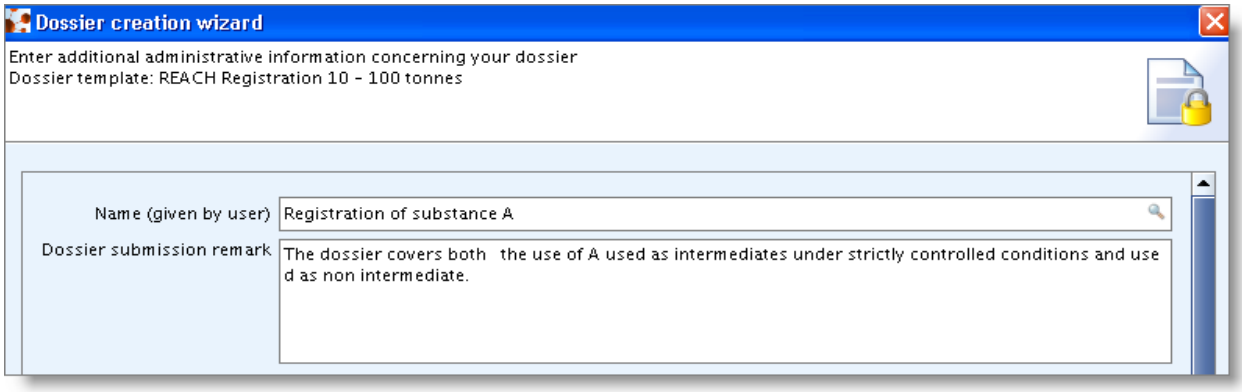

Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Name (given by user)
Dossier submission remark
Dossier submission name and remarks
Type of submission
Joint submission
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band
Information about the intermediates' tonnage band and possibility to mark if the dossier is part of a joint submission.
Submission update
Is the submission an update?
Last submission number
Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
Submission update information (to be filled out only in case of an update)
Registration dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality request
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Specific information related to the dossier: phase-in / non phase-in, accessor revision, confidentiality, data sharing, fee waiver.


Specific information for isolated intermediates
Production and use under stricly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Specific information for isolated intermediates.
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Appendix 5.1 Dossier submission name and remarks (dossier header part 1)

The first part allows you to specify the name of the dossier (Figure 22) as well as any additional information you want to point out.

Figure 22: Specifying the name of the dossier


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 10 - 100 tonnes
Name (given by user)
Registration of substance A
Dossier submission remark
The dossier covers both the use of A used as intermediates under strictly controlled conditions and used as non intermediate.

Appendix 5.2 Type of Submission (dossier header part 2)

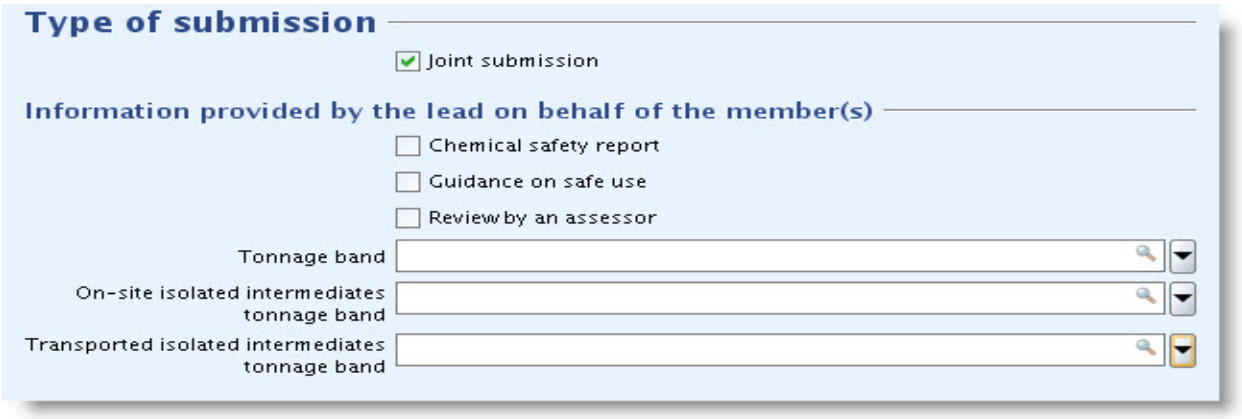
The second part of the dossier header is where information about involvement in joint submission and possible inclusion of intermediates in the registration can be indicated.

If the dossier is a part of a joint submission, the registrant should mark the “Joint submission” tick box. In case the box is marked, further information is required about what is provided by the lead registrant.

When the “Joint Submission” tick box is marked, the “Tonnage band” pick list appears. In case of Joint Submissions, the IUCLID 5 template determines the Joint Submission tonnage band (lead registrant dossiers) or does not indicate a tonnage band at all (member dossiers). Therefore, the submitting company’s annual manufactured/imported tonnage of the substance can only be indicated in this “Tonnage band” field.

If the dossier is a combined submission for non-intermediate and intermediate use, the intermediate tonnage bands need to be indicated in this part of the dossier header.

Figure 23: Type of submission


Type of submission
Joint submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band
On-site isolated intermediates tonnage band
Transported isolated intermediates tonnage band

Appendix 5.3 Submission update information (dossier header part 3)

It is important to identify whether the dossier should be submitted as an update of a previous dossier or not. Please note the following:

If a submitted dossier is marked as an update although it should not be, then it cannot be processed by REACH-IT and the “Submission failure/submission rule violation” message is sent to your REACH-IT inbox.

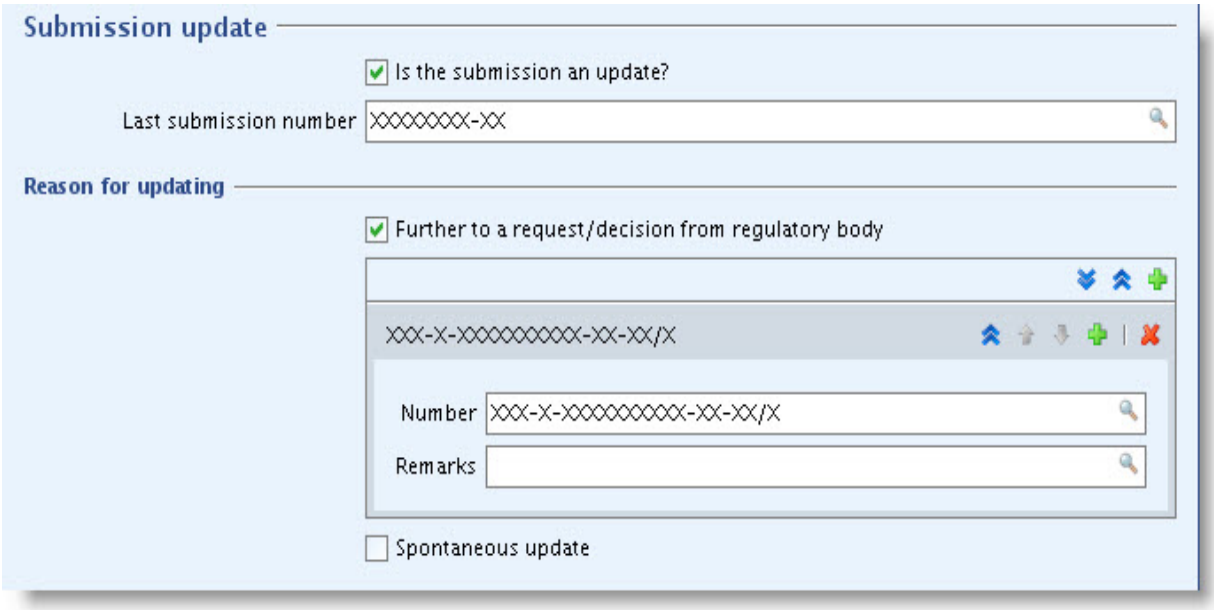
The following situations are the only situations where the submission should be considered as an update:

Appendix 5.3.1 Requested Update for an Incomplete Initial Submission

A registration dossier has been sent before for the same substance, but, although it passed the initial rule verification steps in REACH-IT, the registration was considered as incomplete by ECHA during completeness check. The submission of an updated dossier in this case is meant to fulfil the request for further information made by the Agency within a set deadline. Under these circumstances: the last submission number (i.e. the one attributed to the dossier which resulted in the request for further information) must be reported in the “Last submission number” field; the checkbox “Further to a request/decision from regulatory body” in IUCLID must be selected (Figure 24), and the communication number indicated in the request for further information must be entered in the adjacent “Number” field in IUCLID (see Figure 24).

This only applies to submissions which were considered incomplete by the Agency during the completeness check and which resulted in a letter titled ‘Request for further information on your registration under Regulation (EC) No. 1907/2006’. If you receive a communication of Business Rule validation failure then you should submit the same type of dossier (initial or spontaneous update) with the one that failed Business Rule validation.

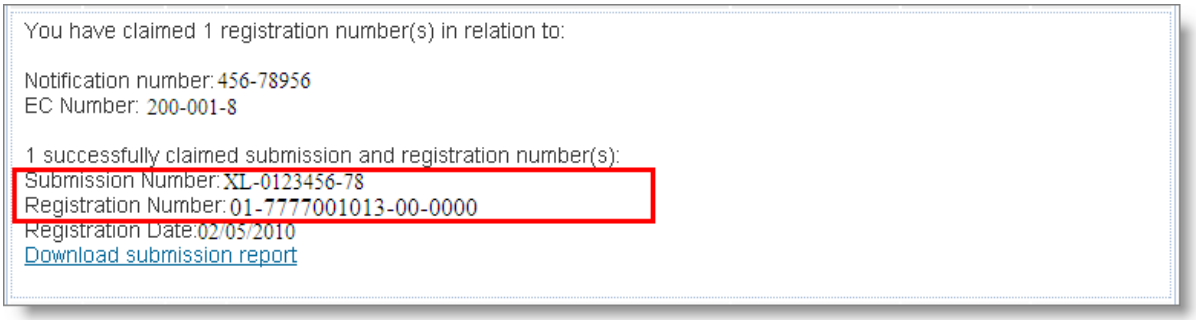
Figure 24: IUCLID screen with reason for updating



Appendix 5.3.2 Updating a Substance Notified Under Previous Legislation (NONS)

The substance is a notified substance under Directive 67/548/EEC (considered as being registered by the claimant under REACH). Before proceeding, you should claim the registration number following the information given in ECHA web site related to the NONS (http://echa.europa.eu/reachit/nons_en.asp). If the claim is successful, you will receive in your REACH-IT mailbox both the registration number and the submission number (Figure 25).

Figure 25: REACH-IT message for successful NONS claim

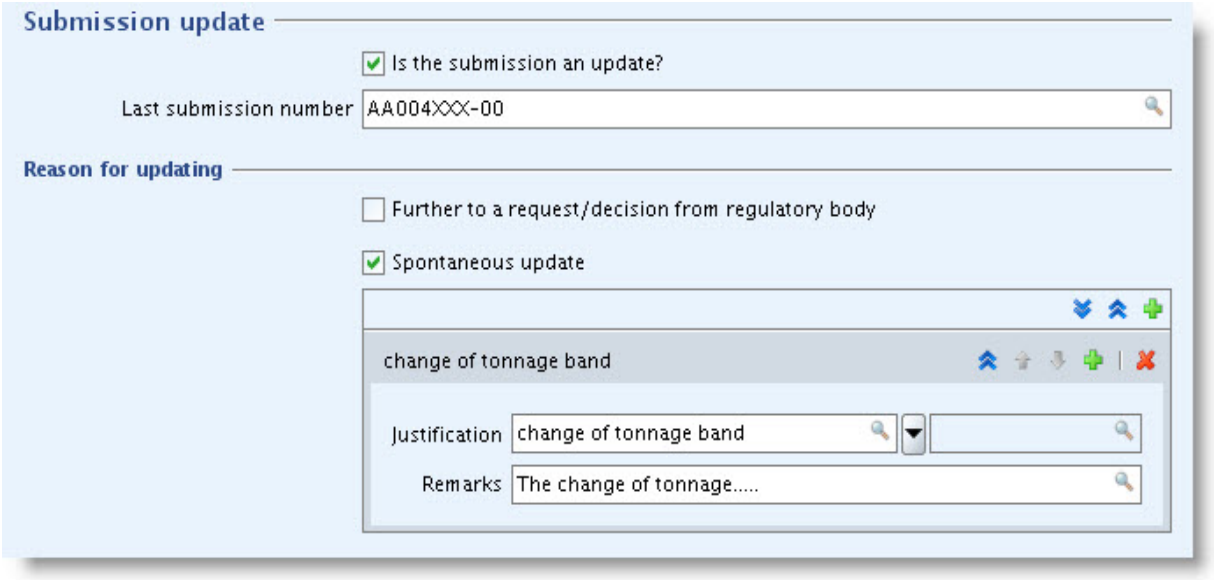

You have claimed 1 registration number(s) in relation to:
Notification number: 456-78956
EC Number: 200-001-8
1 successfully claimed submission and registration number(s):
Submission Number: XL-0123456-78
Registration Number: 01-7777001013-00-0000
Registration Date: 02/05/2010
Download submission report

In order to update your dossier, you should proceed as follows:

- The registration number received should be reported in section 1.3 of the IUCLID 5 dossier.
- The notification number (NCD number) should be reported in section 1.3 of the IUCLID 5 dossier.
- In the dossier header you should indicate, in the “Last submission number” field (Figure 26), the Submission number as indicated in the “Registration number successfully claimed” message.

- Select the checkbox ”Spontaneous update” and specify the reason for the update by selecting it from the drop down list in the “Justification” field (Figure 26).

Figure 26: Updating previous NONS after the claiming of the registration number.



Appendix 5.3.3 Previously Registered Under REACH

The substance was previously registered by your company under REACH. In this case the submission number of the last complete dossier submitted for this substance or the submission number of your update which failed completeness check should be reported in the “Last submission number” field and the registration number should be indicated in the section 1.3 of the IUCLID 5 dossier.

It should also be reported whether the update is an update made on “request from regulatory body” (for example when an update should be submitted following an ECHA completeness check communication or an ECHA compliance check communication) or whether it is a spontaneous update.

If the dossier is an update, it should be identified by all of the following information:

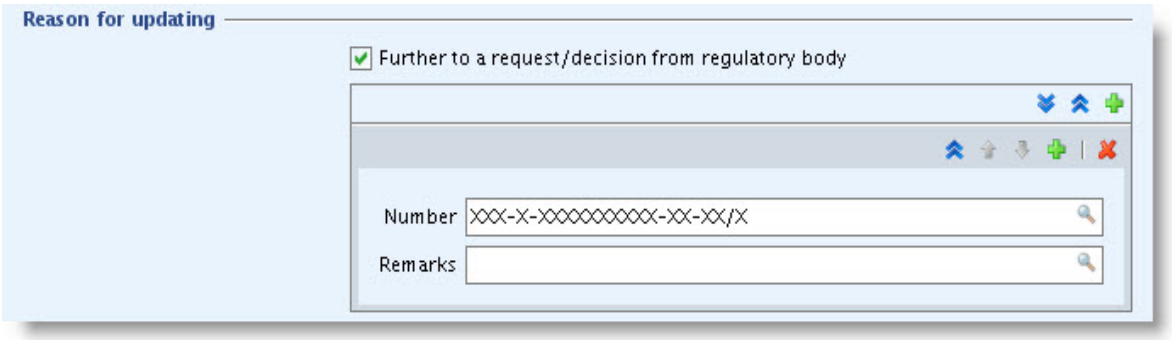
- Ticking the box “is the submission an update”;
- Including the “last submission number” (the number to be given depends on the circumstances described in the succeeding paragraphs);
- Completing the “reason for updating” field.

If the above mentioned information is not provided, ECHA will not be able to process the dossier.

Appendix 5.3.3.1 Update on request

In case of an update made on request of a regulatory body, the checkbox “Further to a request/decision from regulatory body” must be selected and the communication number in the request letter must be entered in the adjacent “Number” field (Figure 27).

Figure 27: Reason for updating - further to a request/decision from regulatory body

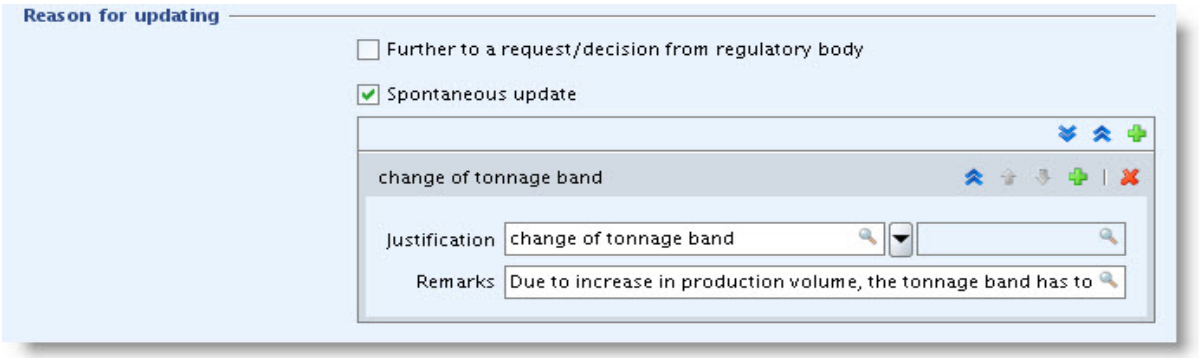


Appendix 5.3.3.2 Spontaneous update

In case of spontaneous update, the checkbox “spontaneous update” should be selected (Figure 28) and the reason for the update should be chosen from the drop down list in the “justification” field (Figure 28). The drop down list is reporting the following update reasons:

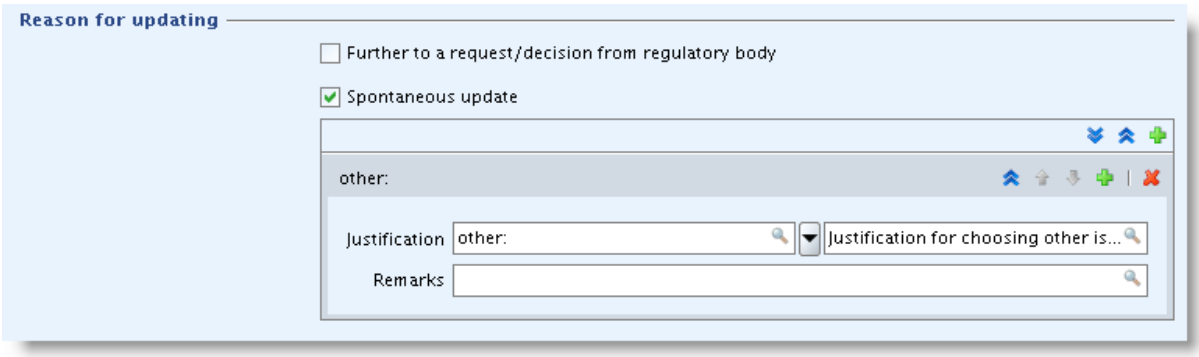
- Change in company identity (NB! This update reason cannot be used in the context of REACH-IT submissions.)
- Change in company role in the supply chain
- Change in composition of the substance
- Change of tonnage band
- New identified uses
- New uses advised against
- New knowledge of the risks for human health and /or environment
- Change in classification and labelling
- New or update of CSR or guidance on safe use
- New testing proposal
- Change in the access granted to information
- Prolongation of exemption period for PPORD
- New uses outside the supplier’s conditions (DU obligations)
- Change in exemptions (DU obligations)
- Other

Figure 28: Reason for updating – spontaneous update


Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Due to increase in production volume, the tonnage band has to

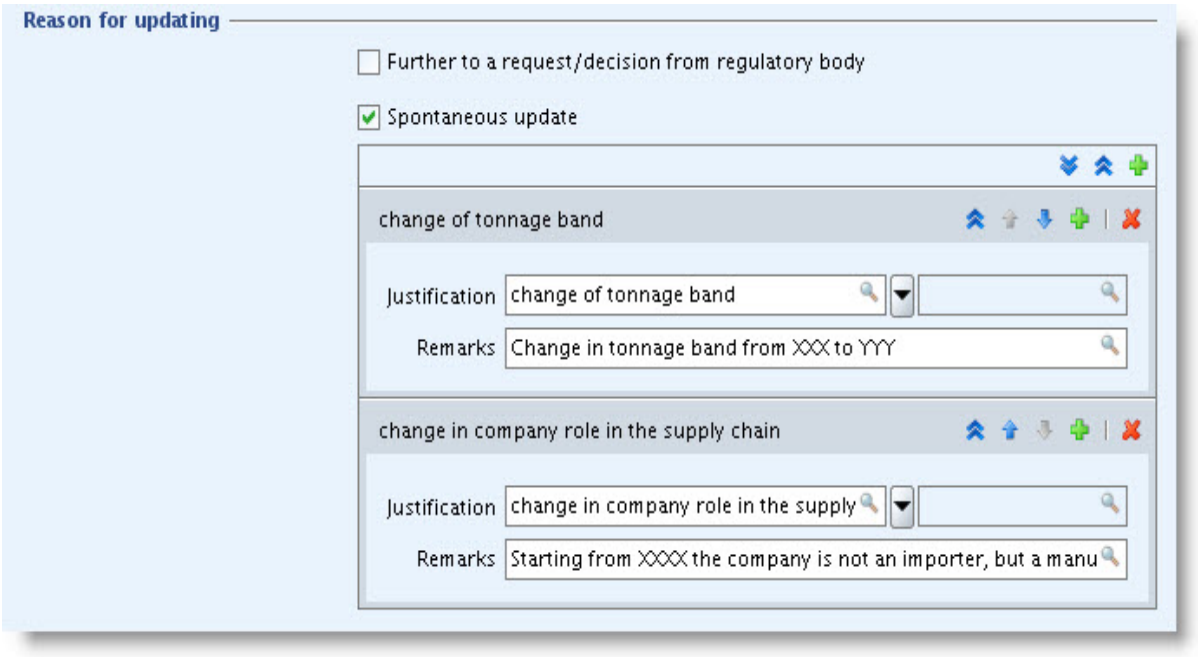
If the reason of the spontaneous update is not listed in the drop down list (for example in case of manufacture cease), the entry “other:” should be selected and the information should be indicated in the corresponding field (Figure 29).

Figure 29: Reason for updating –spontaneous update (other justification)



Finally if you need to indicate more than one reason for updating your dossier, an additional repeatable block should be created for each reason (Figure 30). Please note that a justification has to be provided in all the blocks.

Figure 30: Several reasons for updating – spontaneous update

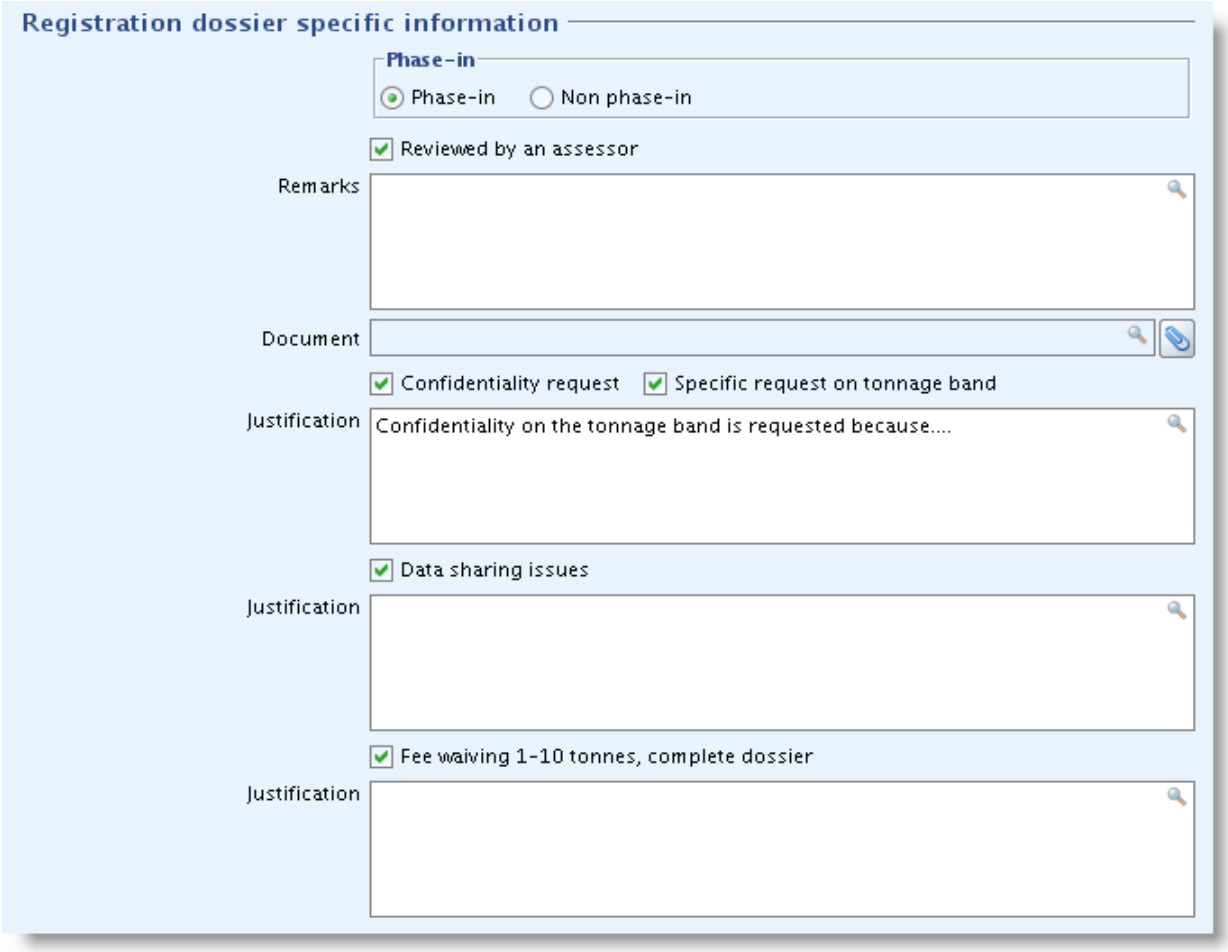

Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Change in tonnage band from XXX to YYY
change in company role in the supply chain
Justification
change in company role in the supply
Remarks
Starting from XXXX the company is not an importer, but a manu

For more information on different types of registration dossiers and the related requirements, refer to the "Guidance on registration" - section 9 (guidance on update of dossier) [http://guidance.echa.europa.eu/].

Appendix 5.4 Specific information related to the dossier (dossier header part 4)

This part of the dossier header allows giving information about the phase-in "status" of the substance, along with more general information on the IUCLID 5 dossier submitted. As a general rule when one of the boxes of the block "registration dossier specific information" (review by an assessor, confidentiality request, fee waiving…) is ticked, the associated free text field below the box should be filled in (example in Figure 31). For more information on how to complete this section of the dossier header, please consult the latest version of the Data Submission Manual 5 (How to Complete a Technical Dossier for Registrations and PPORD Notifications) available from the ECHA website (http://echa.europa.eu/doc/reachit/compl_tech_dossier_manual.pdf).

Figure 31: Registration dossier specific information



The phase-in status has to be marked by selecting either the “Phase-in” or the “Non phase-in” radio button.

Some of the information reported in this block and listed below directly influences the fee calculation; therefore they are part of the Business Rule check.

- Confidentiality request on tonnage band is made in the dossier
- There is a request of fee waiving

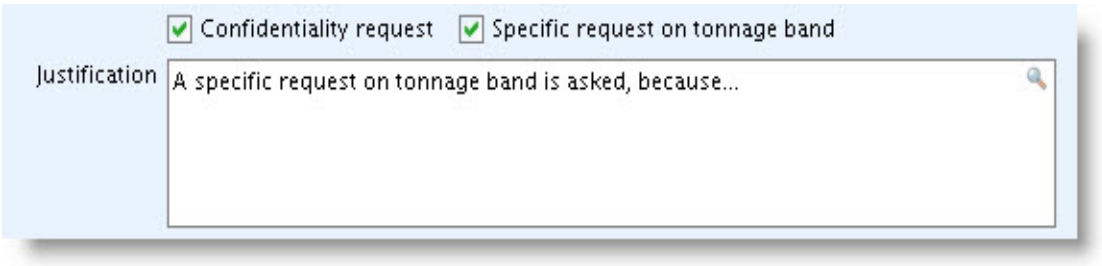
Appendix 5.4.1 Confidentiality

Confidentiality request: the Confidentiality request checkbox in the dossier header can only be used in combination with the “Specific request on tonnage band” to claim confidentiality on the tonnage band. These fields cannot be used for any other type of confidentiality claim. When requesting confidentiality on the tonnage band, both boxes must be ticked, in any other case, the boxes must not be ticked.

Confidentiality request on the tonnage band

If the registrant wants to keep the tonnage band for which he registers as confidential information, the checkboxes “Confidentiality Request” and “Specific request on tonnage band” in the dossier header should be selected, as this is the only way to request the confidentiality flag. A justification must be provided (Figure 32).

Figure 32: Confidentially request on the tonnage band


Confidentiality request
Specific request on tonnage band
Justification
A specific request on tonnage band is asked, because...

The confidentiality flag in section 3.2 of IUCLID 5 cannot be used to request confidentiality for your tonnage band, because that section relates to the actual tonnage manufactured / imported, which is always treated as confidential information.

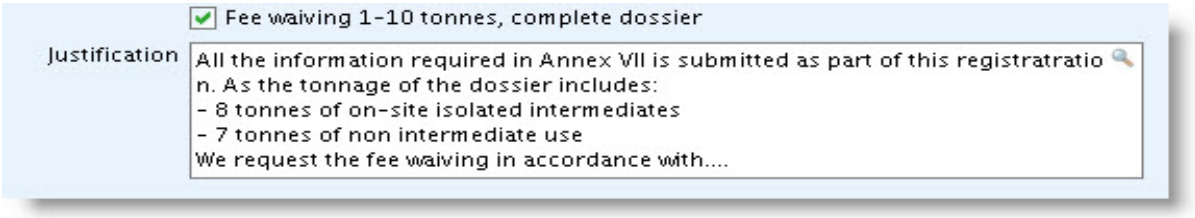
A registrant can request that certain information that is submitted to the Agency according to Art. 10 of the REACH regulation is not published on the internet because publication could be harmful for his or any other concerned party's commercial interests.

All other confidentiality requests must be made in the relevant section of the substance dataset. A justification has to be provided for every confidentiality request. Further information can be found in the latest version of the Data Submission Manual 5 on how to complete a technical dossier for registration and PPORD notification on the ECHA website (http://echa.europa.eu/doc/reachit/compl_tech_dossier_manual.pdf).

Appendix 5.4.2 Fee waiving

Request of fee waiving: Only in case a registration is made for a tonnage below 10 tonnes, an exemption of the fee can be requested if all information required by Annex VII of REACH is provided, in accordance with Art 3(1) and 4(1) of the Fee Regulation (EC 340/2008). In this case the checkbox "Fee waiving 1-10 tonnes, complete dossier" must be selected and a justification must be provided in the appropriate text box (Figure 33).

Figure 33: Request of fee waiving – tick box IUCLID


Fee waiving 1-10 tonnes, complete dossier
Justification
All the information required in Annex VII is submitted as part of this registratratio
n. As the tonnage of the dossier includes:
- 8 tonnes of on-site isolated intermediates
- 7 tonnes of non intermediate use
We request the fee waiving in accordance with....

Appendix 5.5 Specific information for isolated intermediates (dossier header part 5)

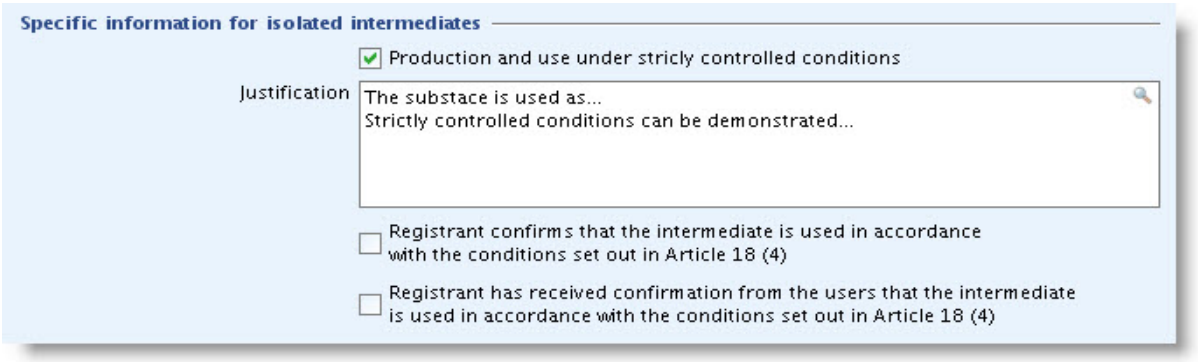
When the dossier covers also a volume used as isolated intermediate, specific information should be reported in the dossier header.

The exemption from standard information requirements only applies to isolated intermediates that are manufactured or used under strictly controlled conditions, and this will be regarded as claimed by the registrant only if the appropriate checkbox is selected (Figure 34).

Please note that the strictly controlled conditions will have to be carefully documented. More information can be found in the 'Guidance on intermediates' available from the ECHA website (http://guidance.echa.europa.eu/).

In addition, different information requirements apply to on-site and transported intermediates and more information can be found in the 'Guidance for intermediates' available from the ECHA website (http://guidance.echa.europa.eu/).

Figure 34: Tick boxes for isolated intermediates


Specific information for isolated intermediates
Production and use under stricly controlled conditions
Justification
The substace is used as...
Strictly controlled conditions can be demonstrated...
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)

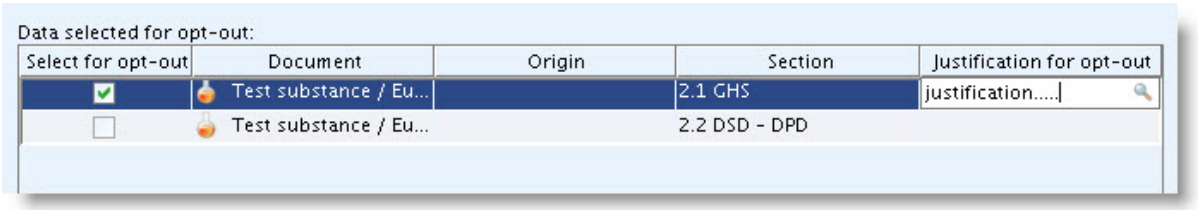
When a dossier is made for a substance used both as isolated intermediates under strictly controlled conditions and as non intermediates, the fees will be calculated as the sum of individual fees for intermediate and non intermediate (as if separate dossiers had been submitted).

Appendix 5.6 Opt outs

Opt out from a joint submission: if the registrant is part of a joint submission and wants to opt out (according to Article 11(3) of the REACH Regulation) by submitting separately information, which should normally be submitted jointly, he should select the sections of the dossier for which the opt-out is requested at the 7th step of the dossier creation wizard. A justification should be provided in the last column for every section selected (Figure 35). Please note, that this step only available in case of a joint submission.

The eventual opt-in for confidentiality claim can be indicated during the submission of the joint member submission dossier. For more information on Joint submission, refer to industry user manual Part 7 (Joint submission) available on the ECHA website (http://echa.europa.eu/doc/reachit/industry_user_manual/reachit_joint_submission_en.pdf).

Figure 35: Indicating opt out in IUCLID

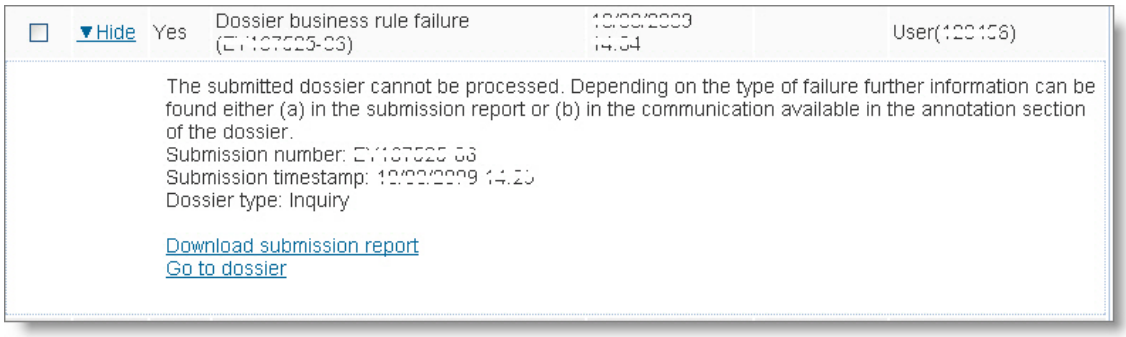


Appendix 6 Finding information about your submission

What happens when a dossier fails an automated business rule?

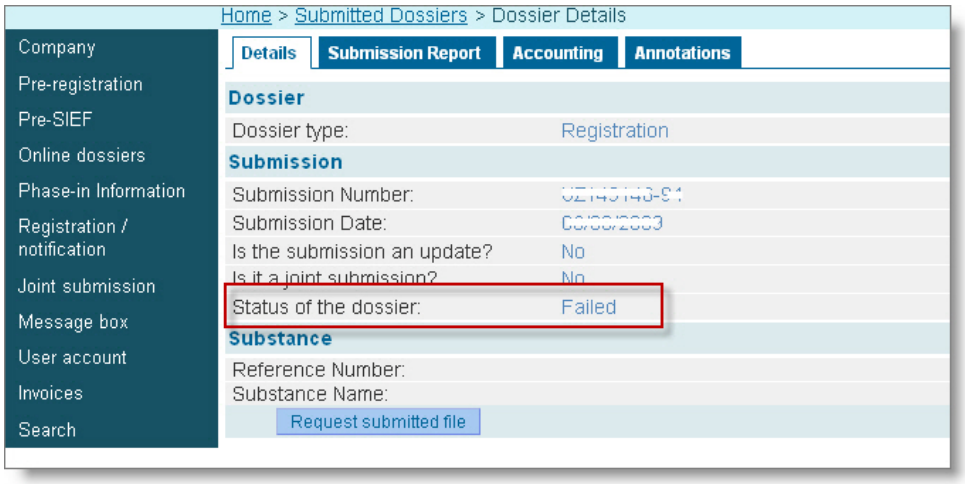
If the submitted dossier fails at the automated business rule step, REACH-IT immediately sends a message to the registrant in the REACH-IT mailbox. In this message, “Dossier business rule failure,” the following information is displayed (see Figure 36).

Figure 36: REACH-IT message on BR failure – auto check


Hide
Yes
Dossier business rule failure
User(
The submitted dossier cannot be processed. Depending on the type of failure further information can be found either (a) in the submission report or (b) in the communication available in the annotation section of the dossier.
Submission number:
Submission timestamp:
Dossier type: Inquiry
Download submission report
Go to dossier

If you click the <Go to dossier> link, you will also notice that in the <Dossier details> tab, the status of the dossier has changed from <Pending> to <Failed> as shown here below (see Figure 37).

Figure 37: Status of a dossier in the dossier details tab

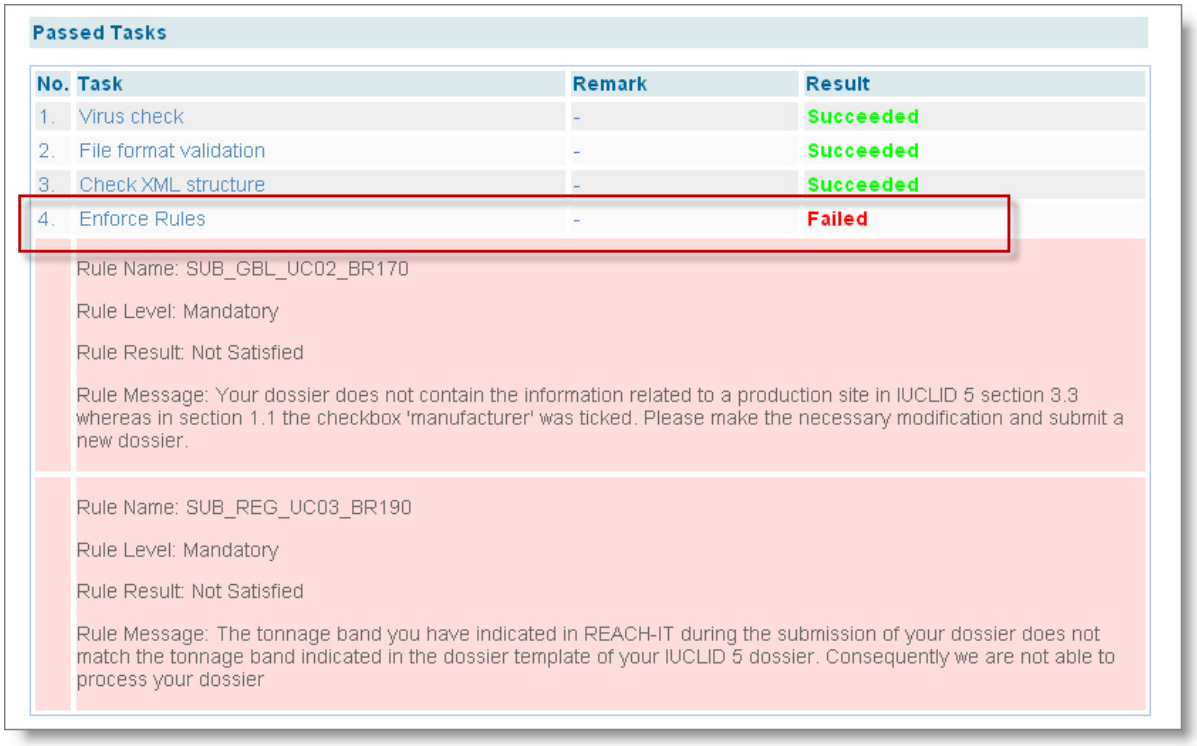


The complete list of the failed automated business rules is available by clicking the tab <Submission Report>. (see Figure 38 and Figure 39)

Figure 38: Tab for checking complete list of failed automated business rules

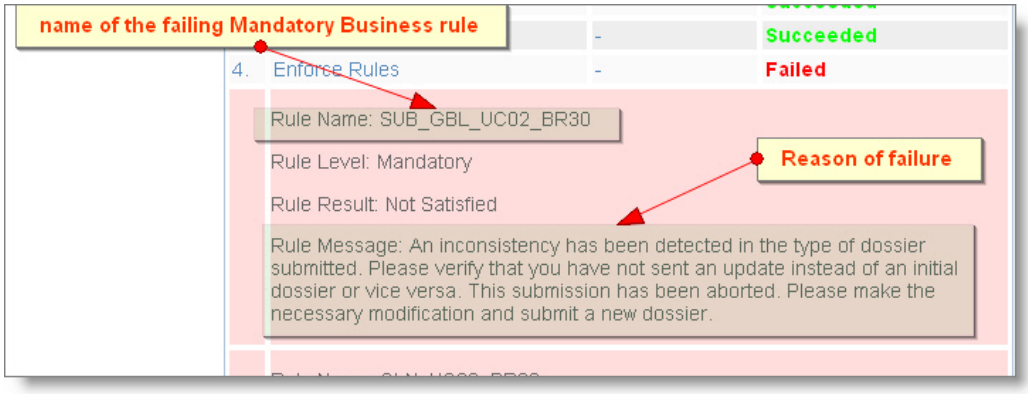
Figure 39 provides an example of how the information on the automated business rules is displayed in the submission report.

Figure 39: Submission report


Passed Tasks
No. Task Remark Result
1. Virus check - Succeeded
2. File format validation - Succeeded
3. Check XML structure - Succeeded
4. Enforce Rules - Failed
Rule Name: SUB_GBL_UC02_BR170
Rule Level: Mandatory
Rule Result: Not Satisfied
Rule Message: Your dossier does not contain the information related to a production site in IUCLID 5 section 3.3 whereas in section 1.1 the checkbox 'manufacturer' was ticked. Please make the necessary modification and submit a new dossier.
Rule Name: SUB_REG_UC03_BR190
Rule Level: Mandatory
Rule Result: Not Satisfied
Rule Message: The tonnage band you have indicated in REACH-IT during the submission of your dossier does not match the tonnage band indicated in the dossier template of your IUCLID 5 dossier. Consequently we are not able to process your dossier

For each failed automated business rule, the <Submission report> gives the reason of failure as indicated in Figure 40.

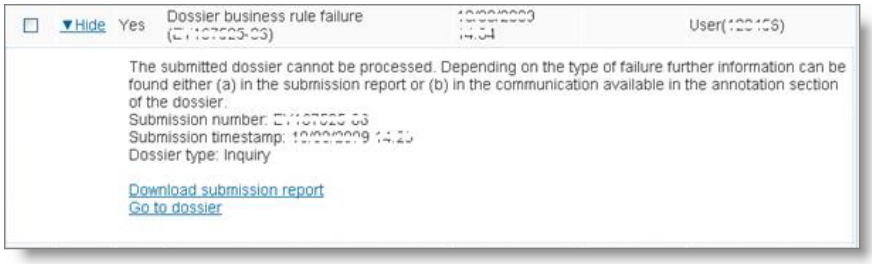
Figure 40: Submission report with details


name of the failing Mandatory Business rule
Succeeded
4. Enforce Rules
Failed
Rule Name: SUB_GBL_UC02_BR30
Rule Level: Mandatory
Reason of failure
Rule Result: Not Satisfied
Rule Message: An inconsistency has been detected in the type of dossier submitted. Please verify that you have not sent an update instead of an initial dossier or vice versa. This submission has been aborted. Please make the necessary modification and submit a new dossier.

What happens when a dossier fails a manually checked business rule?

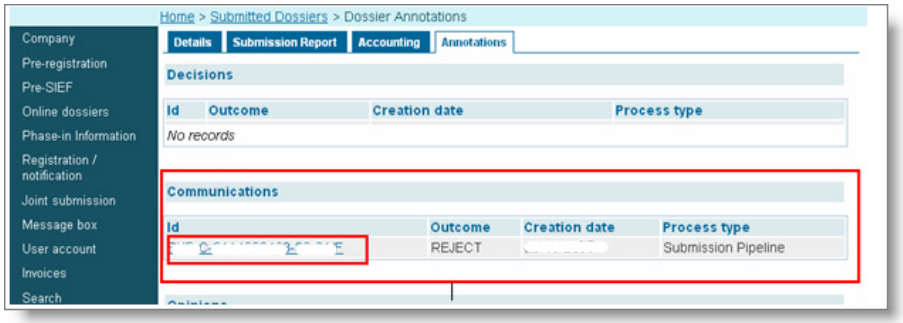
If the submitted dossier cannot be processed due to one or more manually checked business rules, ECHA sends a message to the registrant's/notifier's REACH-IT mailbox. This message entitled <Dossier business rule failure> is displayed in Figure 41.

Figure 41: REACH-IT message on BR failure – manual check


Hide
Yes
Dossier business rule failure
User(
The submitted dossier cannot be processed. Depending on the type of failure further information can be found either (a) in the submission report or (b) in the communication available in the annotation section of the dossier.
Submission number:
Submission timestamp:
Dossier type: Inquiry
Download submission report
Go to dossier

As stated in the message, further information is available in the <Annotation> tab under <Communications> in the dossier. The easiest way to access that information is clicking the <Go to dossier> link, and then click the <Annotations> tab (see Figure 42).

Figure 42: Annotations tab with Communications

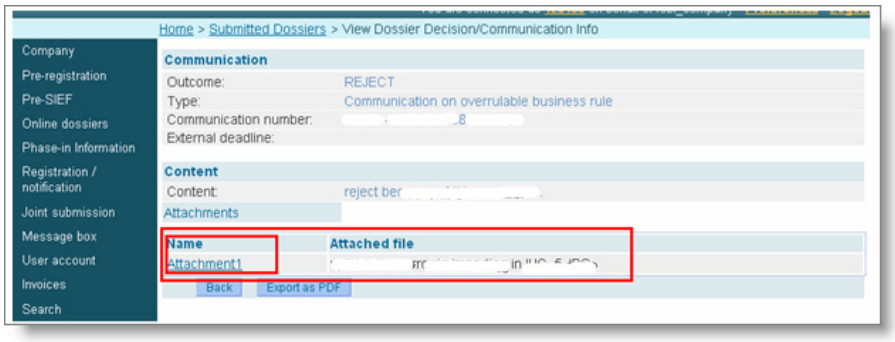


Clicking the link of the <Communication number> (the one in the inner red box in the above screenshot) you will be able to open the attachment (a PDF document, see Figure 43) containing:

- all details on the failure

- the actions you should take to submit a valid dossier.

Figure 43: Attached communication in the dossier info



European Chemicals Agency, PO Box 400, Annankatu 18, FI-00121 Helsinki, Finland. **http://echa.europa.eu**